

CDS Connect Contract Year 2 Final Report



CDS Connect

Final Report (Year 2)

CDS Connect

Prepared for:

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. HHSA290201600001U

Prepared by:

CMS Alliance to Modernize Healthcare, a federally funded research and development center operated by the MITRE Corporation

AHRQ Publication No. 18-0058-3-EF

September 2018

The findings and conclusions in this document are those of the author(s), who are responsible for its content, and do not necessarily represent the views of the Agency for Healthcare Research and Quality (AHRQ). No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

Disclaimer of Conflict of Interest

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

Funding Statement

This project was funded under contract/grant number HHSA290201600001U and HHSM500201200008I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the U.S. Department of Health and Human Services.

Public Domain Notice

This document is in the public domain and may be used and reprinted without special permission. Citation of the source is appreciated.

Suggested Citation

CMS Alliance to Modernize Healthcare. CDS Connect Final Report (Year 2). Prepared under Contract No. HHSA290201600001U and HHSM500201200008I. AHRQ Publication No. 18-0058-3-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2018.

Acknowledgments

Specifically, we want to thank and recognize:

AHRQ leadership team including Dr. Edwin Lomotan, Steve Bernstein, Shafa Al-Showk, Mary Nix, and Ric Ricciardi

The CDS Connect Work Group members supporting the CDS Connect project

OCHIN and health centers from their network

The Patient-Centered Clinic Decision Support Learning Network

The MITRE CDS Connect Project Team

Executive Summary

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ's priority areas of focus are: investing in research to make healthcare safer and improve quality, creating materials to train healthcare systems and professionals to put research results into practice, and generating measures and data used by providers and policymakers.¹ AHRQ's evidence-based tools and resources can be used to propel stakeholders toward improved quality, safety, effectiveness, and efficiency of health care.²

The Patient Protection and Affordable Care Act (ACA) of 2010 directs AHRQ to disseminate and build capacity in patient-centered outcomes research (PCOR). Working with clinical organizations, AHRQ is assisting health information technology (IT) users with incorporating patient-centered research findings expressed as clinical decision support (CDS) into clinical practice. CDS provides patient-specific information and evidence-based knowledge via health IT to clinicians, patients, or other individuals. CDS includes processes and mechanisms that aim to deliver the right information, to the right person, using the right format, in the right channel, and at the right time during workflow (often referred to as the "5 Rights" framework).³ Well-implemented CDS can improve health care decisions and the quality and efficiency of the care provided to patients.

The goals of AHRQ's overall CDS initiative are to advance evidence into practice through CDS, and to make CDS more shareable, health IT standards-based, and publicly available. This effort includes the following components:

1. Engaging stakeholders to catalyze the development and use of PCOR-based CDS throughout the health care system and provide CDS developers and stakeholders with constructive advice and feedback.

¹ <https://www.ahrq.gov/cpi/about/profile/index.html>

² <https://www.ahrq.gov/>

³ Boxwala, AA, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc* 2011(18) i132-i139.

2. Developing prototype infrastructure to create and share CDS, including coded clinical knowledge, implementation guides, and a publicly accessible repository of CDS resources or “artifacts.”
3. Advancing CDS research through demonstration and dissemination grant funding opportunities.
4. Evaluating the overall initiative, including lessons learned and future recommendations.

To realize the second component of this initiative, AHRQ sponsored the CDS Connect project, a contract with CMS Alliance to Modernize Healthcare, a federally funded research and development center operated by the MITRE Corporation. The CDS Connect team developed a production-level “CDS Connect” repository to host and share standards-based, interoperable CDS artifacts (knowledge expressions implemented in EHR systems to inform care) via a web-based, publicly available system. Through the Repository, CDS contributors and CDS consumers have equal access to knowledge generated from cutting-edge CDS research, as well as clinical and regulatory standards. Additionally, organizations that work to balance limited resources can leverage advanced technical resources and secure information critical to the CDS implementation process. Contributions to the Repository grow every day, expanding the breadth of resources available to stakeholders across the Nation.

The CDS Connect project also developed a production-level CDS Authoring Tool that leverages interoperable standards so that CDS can be written to common specifications. This capability was designed to be intuitive and easy to use, with the intention of reducing the development burden that health care organizations undertake. By making it easier to compose and express CDS artifacts, this software improves the quality of CDS design, accelerates the velocity of CDS development, ensures open access to supporting CDS resources, and enables integrated software systems for interoperable CDS. Furthermore, the code for this system is open-source, enabling greater access, adoption, and community involvement.

To demonstrate a repeatable CDS development process and the Repository’s capability to host and share CDS in this second year of the project, the CDS Connect team developed, tested, and implemented a CDS artifact that generated a summary view of patient data relevant to pain management. The “Pain Management Summary” markedly reduced clinician burden by compiling clinical data that normally needs to be searched for across several

sections of an EHR. Documentation and sharing of the development and implementation processes promotes transparency and increased awareness to future developers and implementers—furthering efficiency and effectiveness.

Key to all streams of work, CDS Connect leaders hosted a monthly Work Group meeting attended by a broad array of CDS stakeholders (subject matter experts from across government, industry, academia, clinical settings, and nonprofits) and conducted outreach via conference presentations, demonstrations, webinars, and strategic discussions to inform and maximize work efforts and increase adoption of the CDS Connect systems.

This second year of the CDS Connect project enabled the two central systems (the Repository and Authoring Tool) to be developed into robust, valuable assets to the health care and CDS communities. This work provides the framework for improving health care outcomes via CDS creation, discovery, integration, and implementation using evidence-based interoperable CDS artifacts.

Table of Contents

Final Report (Year 2)	i
CDS Connect	i
Disclaimer of Conflict of Interest	i
Funding Statement.....	i
Public Domain Notice	i
Suggested Citation.....	i
Acknowledgments	ii
Executive Summary	iii
Table of Contents	vi
List of Figures	vii
List of Tables	vii
Introduction	1
Task Reports	10
Task 1. Task Management	10
1.1. Operational Leadership	10
1.2. Stakeholder Engagement.....	10
1.3 Project Milestones.....	13
Task 2. Develop PCOR CDS Artifacts.....	14
2.1. Impacting Pain Management and Opioid Prescribing with CDS	14
2.2 Additional Artifacts Developed in Year 2	26
Task 3. Pilot PCOR CDS Artifacts	29
3.1. Pilot Site Characteristics and Selection	30
3.2. Pilot Implementation Planning	31
3.3. Pilot Site Technical Integration	31
3.4 Analysis of the Pain Management Summary	32
Task 4. Develop Prototype Tools for Sharing PCOR CDS Artifacts	34
4.1 Production Level CDS Repository	34
4.2 Prototype Tools.....	39
Task 5. Maintain Stakeholder Working Group.....	41

Task 6. Hosting and Maintaining Prototype Tools	42
Task 7: Prototype Authoring Tool and Related APIs	43
7.1 Open Source Status	49
Lessons Learned	50
Recommendations.....	52

List of Figures

Figure 1: CDS Connect Project Logo	2
Figure 2: CDS Connect Repository Concept of Operations.....	3
Figure 3: HIMSS Interoperability Showcase Value Based Care Team Members	12
Figure 4. The Pain Management Summary user interface	22
Figure 5. HIMSS IS: Value Based Care Use Case and Participating Organizations.....	28
Figure 6. Semi-structured Representation of the Longitudinal ASCVD Risk Tool	29
Figure 7. Notional Depiction of Groups Capability on CDS Connect	36
Figure 8. The CDS Hooks Sandbox Demonstrating a CQL Services CQL Hook.....	40
Figure 9. CDS Connect Repository Link to the CDS Authoring Tool	45
Figure 10. Sequence for Creating Element Using VSAC Integration	46
Figure 11. Expression Phrases in Complex Data Elements.....	47
Figure 12. CDS Testing Screen Supporting Patient Upload and CQL Execution.....	48
Figure 13. Example CDS Testing Results for a Synthetic Patient Matching the Inclusion Criteria.....	48
Figure 14. The CDS Authoring Tool on GitHub.....	50

List of Tables

Table 1 Key Project Activities and Work Products	4
Table 2. Final Semi-Structured Inclusion and Exclusion Logic	18
Table 3. Final Semi-Structured CDS Intervention logic.....	18
Table 4. Published Artifacts That Were Contributed by External Stakeholders	37

Introduction

The Agency for Healthcare Research and Quality (AHRQ) is charged with producing evidence to make health care safer, better, and more accessible, equitable, and affordable. AHRQ works within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence produced is understood and, most importantly, that it is used. One AHRQ priority is to improve health care quality by accelerating the real-world clinical implementation of patient-centered outcomes research (PCOR).

AHRQ has requirements related to disseminating PCOR findings and clinical decision support (CDS). CDS provides patient-specific information and knowledge to clinicians and others using health information technology (IT). AHRQ supports users of health IT and CDS by incorporating PCOR findings into clinical practice. In addition, AHRQ helps to establish a process for receiving feedback from stakeholders, including providers, patients, and vendors about the value of the information and the assistance provided.

AHRQ asked the CMS Alliance to Modernize Healthcare (CAMH) federally funded research and development center (FFRDC) to help launch an initiative to promote the dissemination and implementation of PCOR findings. Specifically, AHRQ tasked CAMH to generate a systematic and replicable process for transforming PCOR findings into shareable, health IT standards-based, publicly available CDS, and to develop prototype tools to facilitate this transformation process.

The MITRE Corporation (MITRE), as the operator of the CAMH FFRDC, supported AHRQ with this project, which included the development, implementation, and integration of health information tools, products, and systems. This project, named “CDS Connect,” aimed to improve the quality of CDS design, accelerate the velocity of CDS development, ensure open access to supporting CDS resources, and enable integrated software systems for interoperable CDS “artifacts” to support the dissemination of PCOR CDS artifacts to U.S. health care practices and associated health IT developers.



Figure 1: CDS Connect Project Logo

The term “artifacts” has been deliberately embraced by the CDS Connect project to provide the ability to support a variety of CDS types or interventions that are not exclusively limited to the space of clinical alerts (which is commonly attributed with “CDS”). The term artifacts can apply to a variety of CDS interventions, including notifications, order sets, documentation templates, dashboards, etc. This provides flexibility in inviting participation in the CDS Connect project with a broader set of approaches and stakeholders in the CDS space.

In the first period of performance (PoP) the CDS Connect project:

- Developed and released a publicly accessible beta-level CDS repository (the CDS Connect Repository), which hosts and shares standards-based, interoperable CDS artifacts with the public
- Designed and released an alpha-level CDS Authoring Tool (AT) and associated application programming interfaces (APIs) to facilitate and ease the development of standards-based CDS artifacts
- Developed six CDS artifacts in the cholesterol management domain (two structured artifacts and four semi-structured artifacts) and posted them on the Repository
- Piloted a CDS Connect-developed artifact in a clinical setting to document implementation efforts, lessons learned, and enhancements to the piloted artifact
- Established two work groups comprising a broad range of CDS stakeholders to inform all aspects of CDS Connect work. One work group had a clinical focus (Cholesterol Management Work Group) and the second had a broader CDS, health IT, systems focus (Repository Work Group)

Figure 2 provides a visual depiction of the CDS Connect concept of operations. It portrays the Repository and AT as central, key facilitators to developing and sharing evidence-based CDS, and a diverse group of individuals using the systems as contributors and end users of the CDS (where the CDS is integrated in EHR systems and presented to clinicians and other targeted individuals).

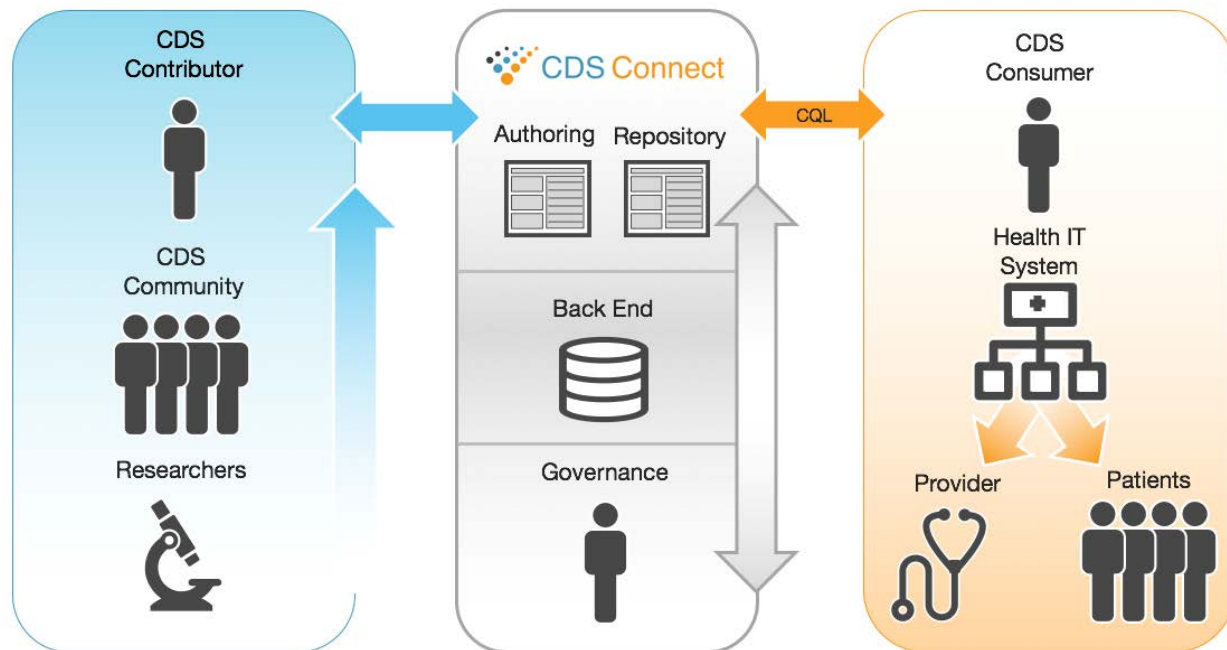


Figure 2: CDS Connect Repository Concept of Operations

CDS Connect project efforts in the second PoP (i.e., Year 2) are outlined in the seven tasks enumerated below and in Table 1.

1. Task Management
2. Develop PCOR CDS Artifacts
3. Pilot PCOR CDS Artifacts
4. Develop Prototype Tools for Sharing PCOR CDS Artifacts
5. Maintain Stakeholder Work Groups
6. Host and Maintain Prototype Tools
7. Prototype Authoring Tool and Related APIs

These tasks build on work completed in the first year by enhancing the Repository and AT systems to production level, developing new prototype tools that enhance CDS implementation and sharing, and refining the CDS development process through the creation of new CDS.

Table 1 Key Project Activities and Work Products

Task	Key Activities	Key Work Products
1	<p>Facilitated leadership meetings</p> <p>Administered sprint planning and burn down meetings</p> <p>Led sponsor engagement, staff management, deliverable management, and financial management</p> <p>Conducted outreach meetings and calls with stakeholders to share the CDS Connect project</p> <p>Developed presentations and demonstrations for numerous conferences and meetings</p> <p>Collaborated with a broad variety of CDS stakeholders (e.g., other developers, government agencies, researchers), including other AHRQ-sponsored work groups (e.g., Trust Framework Work Group from the Patient-Centered CDS Learning Network)</p> <p>Updated the Concept of Operations (CONOPs) to orient stakeholders to the work</p> <p>Developed and updated the Project Work Plan to reflect work effort</p>	<p>Leadership meeting agendas and briefings</p> <p>Sprint planning and burn down meeting notes</p> <p>CDS Connect briefings and conference presentations</p> <p>Updated CONOPs visualization</p> <p>Project Work Plan</p> <p>Final Variance Report</p> <p>Final Project Report</p>

Task	Key Activities	Key Work Products
2	<p>Formed a multidisciplinary artifact development team including clinicians, informaticists, and a group of developers who could create and formally test clinical quality language (CQL) code</p> <p>Conducted and documented an Environmental Scan on CDS in opioid prescribing and pain management domain</p> <p>Collaborated with government program offices responsible for the CDS “Source” clinical practice guidelines</p> <p>Conducted outreach during Work Group and collaborative discussions to improve and inform artifact specifications</p> <p>Translated evidence to semi-structured and structured CDS representations of the evidence</p> <p>Researched existing value sets and developed 13 new value sets to express the required data concepts</p> <p>Documented artifact work via decision log entries, annotated code, and Implementation Guides</p> <p>Conducted a multidisciplinary quality review of the artifact, then thoroughly tested the final code</p> <p>Enhanced the CQL expression based upon pilot findings</p>	<p>Environmental Scan</p> <p>Intellectual Property Report</p> <p>Three structured artifacts for publication on the CDS Connect Repository</p> <p>Textual Reports for the new and updated artifacts</p> <p>Artifact Implementation Guides and decision logs</p> <p>Enhanced Artifact Report</p>

Task	Key Activities	Key Work Products
3	<p>Developed the Pilot Plan</p> <p>Outlined ideal pilot site characteristics</p> <p>Identified potential pilot organizations and socialized the pilot opportunity</p> <p>Selected a pilot organization (i.e., OCHIN) and secured an executed subcontract</p> <p>Secured Institutional Board Review (IRB) approval</p> <p>Developed the pilot Work Plan and led the pilot kick-off meeting</p> <p>Held weekly operational and technical calls</p> <p>Developed an Analytic Plan and training materials</p> <p>Assisted the OCHIN pilot team with integration, testing, and implementation tasks</p> <p>Led clinician training for the pilot organization</p> <p>Participated in troubleshooting and resolution of issues as they arose</p> <p>Led focus group discussions with CDS end-user clinicians</p> <p>Developed the Pilot Final Report</p>	<p>Pilot Plan</p> <p>Executed contract with OCHIN</p> <p>IRB approval</p> <p>Developed pilot Work Plan, Analytic Plan, Training Plan, and training materials</p> <p>Focus group questions and feedback</p> <p>Pilot Final Report</p>

Task	Key Activities	Key Work Products
4	<p>Established a skilled team with Drupal development and design expertise</p> <p>Performed regular Drupal updates to all modules</p> <p>Implemented a Digital Millennium Copyright Act complaint form on the CDS Connect Repository for allowing users of the site to assert when artifacts infringe on their copyrighted material</p> <p>Added “Topics” to the CDS Connect Repository to allow for better organization and presentation of artifacts</p> <p>Added Foresee customer satisfaction survey to the CDS Connect Repository</p> <p>Expanded the Representational State Transfer (RESTful) capabilities of the CDS Connect Repository by adding two additional APIs</p> <p>Refined the artifact authoring workflow and site governance by including the ability to organize users of CDS Connect Repository into “groups”</p> <p>Developed a Prototype Tool (CQL Services) for exposing CQL CDS through custom RESTful APIs and CDS Hooks-compliant APIs, moving the tool from Alpha to Beta, and now Production level</p> <p>Completing requirements to make the Prototype Tool (CQL Services) open source</p>	<p>Live web-based production-level CDS Connect Repository https://cds.ahrq.gov/</p> <p>Biweekly Sprint Planning and Sprint Burndown meeting notes</p> <p>Source code for production version of CDS Connect Repository, with continued updates as needed</p> <p>CDS Connect Repository Performance Document</p> <p>CDS Connect March 2018 Working Group: Groups and Artifact Workflow Modifications (Technical Briefing)</p> <p>CDS Connect July 2018 Working Group: Draft User’s Guide (Technical Briefing)</p> <p>CDS Connect: An Online Repository Built using Open Source Software (Technical Briefing)</p> <p>Alpha, Beta, and now Production-level Prototype Tool (CQL Services)</p>

Task	Key Activities	Key Work Products
5	<p>Recruited Work Group members</p> <p>Developed and shared a Work Group Charter</p> <p>Identified a Chairperson for the Work Group</p> <p>Developed and disseminated monthly agendas, presentations, and meeting summaries</p> <p>Collaborated via email and offline conversations to further project objectives</p>	<p>Work Group Charter</p> <p>Work Group Agendas</p> <p>Work Group Meeting Notes</p> <p>Public Release System approval for meeting notes and power point presentations published on the CDS Connect Repository</p> <p>Final List of Work Group Members and their organizations</p>
6	<p>Integrated Lightweight Data Access Protocol (LDAP) into CDS Connect Repository to allow for single-sign-on between Repository and CDS Connect Authoring Tool</p> <p>Applied numerous software updates to the CDS Connect Repository, including a major upgrade to the underlying Drupal web application as well as several critical security patches</p> <p>Facilitated user account setup and maintenance</p>	<p>Publicly accessible instance of CDS Connect Repository and Authoring Tool at https://cds.ahrq.gov</p> <p>Bimonthly updates to CDS Connect Systems Document</p> <p>Biannual updates to the Service Level Agreement document</p>

Task	Key Activities	Key Work Products
7	<p>Conducted Sprint Planning and Burndown Meetings</p> <p>Configured automated continuous integration and deployment environments</p> <p>Implemented user accounts</p> <p>Responded to user account requests and user feedback/questions</p> <p>Developed Beta-level AT</p> <p>Expanded ability to enable users to select the clinical domain and relevant value sets to express their CDS</p> <p>Developed Production-level AT</p> <p>Implemented ForeSee customer satisfaction survey</p> <p>Implemented back-end support for the National Library of Medicine (NLM) new Fast Healthcare Interoperability Resources (FHIR) API</p> <p>Enhanced the user interface (UI), improving user experience</p> <p>Enhanced elements and parameter types</p> <p>Resolved identified bugs</p> <p>Developed user-facing testing with synthetic data</p> <p>Developed a Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR application to serve as the CQL integration engine</p>	<p>Beta and ultimately Production-Level AT and associated APIs</p> <p>Open source status</p> <p>Updates to the Service Level Agreement</p> <p>Updated User Guide</p> <p>Enabled testing of CDS developed in the AT</p> <p>Expanded capability to support a broad range of Conditions, Observations, Medications and Treatments</p>

Task Reports

Task 1. Task Management

1.1. Operational Leadership

The CDS Connect project's Leadership Team managed the project tasks. The team included a Project Leader (PL), Associate Project Leader (APL), Technical Lead, Clinical Lead, and respective Task Leads. The Leadership Team met throughout the period of performance to ensure work objectives were met and that emerging opportunities were discussed, prioritized, and integrated when appropriate. As warranted, the CDS Connect team worked with AHRQ to schedule and conduct both virtual and in-person site meetings at AHRQ. This project was aided by several subcontractors, including Danny vanLeeuwen (who provided a patient perspective on work efforts) and OCHIN (the pilot organization for the CDS artifact developed during this PoP).

In addition to Leadership Team meetings, the CDS Connect Project was managed through biweekly agile "sprints." Sprints were planned and reported on at the beginning and end of a 2-week sprint interval. Sprint meetings included the AHRQ Government leadership team and the CDS project team. One of the project's formal deliverables was the sprint meeting notes. All sprint activities were tracked using Jira. Jira is AHRQ's web-based planning and execution tool that provides support for implementing agile software development processes and transparency around the development of new features and functionality of the CDS Connect project.

All CDS Connect project members were provided with the ability to access and edit tasking in Jira. The CDS Connect PL or APL reviewed and assigned work in the Jira project board in advance of meetings to ensure status updates and add, remove, or modify tasks to manage project scope and execution. This agile approach and the tools provided value for AHRQ and ensured high-quality work. Further, this approach allowed for better planning and management of competing priorities related to new capabilities for the CDS Connect software systems.

1.2. Stakeholder Engagement

Significant outreach took place across the CDS Connect project that influenced the development and refinement of CDS artifacts, the CDS Connect Repository, and the Authoring Tool. The CDS Connect project used both formal and informal stakeholder engagement. Formal stakeholder engagement occurred through the public Work Group that

is detailed in [Section 5](#) of this report. Informal stakeholder engagement occurred throughout the project via in-person and virtual outreach and dissemination efforts (e.g., webinars, conference calls, conference participation, presentations).

CDS Connect leadership attended numerous conferences during the PoP to raise awareness of the effort, encourage engagement, and identify new opportunities for collaboration to further the project mission. Presentations at and participation in three key conferences generated or strengthened avenues for partnership:

- American Medical Informatics Association. A systems demonstration and panel presentation familiarized attendees with project efforts and tools, resulting in: an ongoing collaboration with CDC contractors developing CDS in the opioid prescribing domain; conversations with several organizations that voiced interest in serving as pilot sites; discussions with CDS researchers working in the pain management and opioid prescribing domain, which informed artifact development.
- Healthcare Information and Management System Society (HIMSS). A systems demonstration and participation in the Interoperability Showcase (Figure 3) provided demonstrable evidence of the usefulness and interoperability of CDS Connect systems, resulting in: important conversations with other Government agencies working in the CDS arena to align and inform efforts, introduced the CDS Connect tools to a broader spectrum of stakeholders developing innovative interoperable resources to improve health care, strengthened relationships with key stakeholders who also attended the conference.



Figure 3: HIMSS Interoperability Showcase Value Based Care Team Members

- Mobilizing Computable Biomedical Knowledge. Presence at the conference and a demonstration of the CDS Connect systems and tools facilitated the potential for future collaboration with the NLM and the Healthcare Services Platform Consortium and a renewed commitment by a Government agency to contribute a significant amount of the CDS artifacts to the CDS Connect Repository.

The CDS Connect team also developed and led presentations for a varied group of stakeholders to raise awareness of the availability and functionality of the Repository and AT systems; disseminate the team's experience in translating evidence-based research into CDS expressions; share insight on the intersection of CDS and electronic clinical quality measures (eCQMs), including where common efforts can be leveraged; and communicate lessons learned during CDS artifact development. Audiences included attendees of CDC's *Adapting Clinical Guidelines for the Digital Age* multi-stakeholder event and members of the CMS's eCQM Governance Committee. In addition, CDS Connect members participated in work groups of the Patient-Centered CDS Learning Network, another AHRQ-sponsored project, to research and establish a Trust Framework for CDS sharing (i.e., the Trust Framework Work Group) and to develop an Opioid Action Plan to apply patient-centered CDS interventions to improve pain management and opioid use (i.e., the Opioid Action Work Group).

Relationships were established and maintained with a variety of stakeholder groups, including Federal agencies (i.e., Centers for Medicare & Medicaid Services [CMS], Center for Medicare and Medicaid Innovation, Veterans Health Administration, NLM, National

Institute for Occupational Safety and Health, and other CDC program offices); academic institutions (i.e., Arizona State University, University of Michigan, and Yale University); clinical decision support vendor organizations (i.e., Cerner and General Electric); health care provider organizations (i.e., Children’s Hospital of Philadelphia, Yale New Haven Hospital); health center controlled networks (i.e., AllianceChicago and OCHIN); research organizations (i.e., Weitzman Institute); former and present AHRQ grantees (e.g., Rick Shiffman, Prashila Dullabh, Nitu Kashyap, Chris Hale); and a patient advocate (Danny vanLeeuwen). Mr. vanLeeuwen provided a patient perspective on all streams of CDS Connect work and significantly informed how the CDS developed by the project team could be most effectively used to provide patient-centered care. Mr. vanLeeuwen also created a blog to be posted on the CDS Connect Repository that urges CDS developers and implementers to consider patient needs and their perspective when working in the CDS domain, since health outcomes cannot be improved without patient buy-in and their participation in care-related decision making.

1.3 Project Milestones

The CDS Connect project had noteworthy milestones during the second year of performance, including the following releases:

- Production-level CDS Connect Repository and API that enables uploading, hosting, and sharing of CDS artifacts, providing access to resources that can improve the quality of care across the Nation
- Production-level CDS Authoring Tool, which eases and facilitates the creation of standards-based, interoperable CDS
- Open-source Authoring Tool code base, allowing the larger CDS community to use, build upon, and re-share the code
- Open-source CQL Services Prototype Tool (planned for September 2018 release), that can be used to deliver CQL-based CDS as a service, changing the delivery approach for CDS
- Pilot-tested, enhanced Pain Management Summary CDS artifact and an accompanying open-source SMART on FHIR app (planned for September 2018 release) to integrate and display the CDS in EHRs, promoting informed pain management decision making and patient-centered care to all end users

Each of these milestones progressed the overarching mission of advancing evidence-based research into clinical care using CDS artifacts. CDS Connect efforts in the third year will

build upon this momentum, guided by stakeholder insight, with an eye toward sustainability of the systems, tools, and resources that have been established.

Task 2. Develop PCOR CDS Artifacts

A key goal of CDS Connect artifact development is ensuring that the Repository has the capacity to convey relevant information for each artifact via deliberately selected, pertinent metadata. Informed by CDS development and external contributions, metadata helps CDS contributors describe the purpose, intended population, evidence-based references, human-readable logic, cautions, pilot findings, and more to Repository viewers. Likewise, work products produced during artifact development highlighted the need to support varied pertinent attachments (e.g., coded logic, test patients, implementation details). Enabling robust communication of artifact details enhances Repository viewers' understanding of the artifact and ultimately their trust in the artifact.

Another key goal of the project is to support data interoperability. MITRE expended significant effort to align standards and re-purpose previous investments from U.S. Department of Health and Human Services (HHS) programs. To achieve this, MITRE used the Health Level 7 (HL7) FHIR Draft Standard for Trial Use 2 (DSTU2) data model to express clinical concepts, and CQL (a HL7 standard for expressing clinical knowledge as CDS). CQL-expressed artifacts are EHR-agnostic and thus interoperable on an international level. Further, use of the CQL standard complements CMS' efforts to pivot to the CQL standard for expressing eCQM logic. This alignment of logic expressions should reduce software developer requirements for commercial vendors and reduce provider burden by focusing on a consolidated number of standards to promote evidence-based health care.

In addition to the inherent utility of the interoperable artifacts, MITRE's experience during the development process is documented and shared via the CDS Connect Repository to provide procedural insight to CDS developers and related stakeholders. The artifact development process involves translating evidence-based guidelines into structured code—a very arduous and, at times, subjective process. Interpretations of the published guidelines and decisions made when coding specifications of each artifact are thoroughly outlined and published in an Implementation Guide that accompanies each MITRE-created artifact. Transparency of the translation process also affects trust in the artifact and highlights decision points that future implementers may choose to adjust for their distinct need.

2.1. Impacting Pain Management and Opioid Prescribing with CDS

Opioids (including prescription opioids, heroin, and fentanyl) killed more than 42,000 people in 2016, more than any year on record.⁴ Forty percent of all opioid overdose deaths involve a prescription opioid. HHS has demonstrated its commitment to addressing opioid abuse, dependence, and overdose by developing a five-point comprehensive strategy: 1) better data; 2) better pain treatment; 3) more addiction prevention, treatment, and recovery services; 4) more overdose reversers; and 5) better research.⁵ AHRQ's decision to focus CDS development on improving pain management and evidence-based opioid prescribing is one demonstration of a larger, concerted Government effort to address opioid misuse and dependence through more informed, evidence-based management of chronic pain.

Treating patients with pain, especially chronic pain, is extremely complex. For this reason, the MITRE team conducted an environmental scan of the chronic, non-cancer pain management landscape to gain awareness of the standards of care and identify evidence-based recommendations and tools that could contribute to the development of new patient-centered CDS artifacts. The published report, available on the CDS Connect website,⁶ identified a wealth of material that informed CDS Connect efforts during artifact conception and specification.

2.1.1 CDS Development Approach

CDS development is usually inspired by one or more evidence-based recommendation statements or clinical practice guidelines. Once identified, the development team applies the “5 Rights” to the source content to design and build the CDS (i.e., presenting the right information, to the right person, in the right format, through the right channel, at the right time).⁷ Based on environmental scan findings, the MITRE team selected the CDC's *Guideline for Opioid Prescribing for Chronic Pain* as the evidence-based source for the pain management CDS. Of note, through outreach outlined in the Task Management section, AHRQ and MITRE had the benefit of collaborating with members of the CDC program office overseeing the opioid prescribing guideline. The collaboration provided an

⁴ Hedegaard H, Warner M, and Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017/ CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>

⁵ United States Department of Health and Human Services. Help, Resources and Information: National Opioid Crisis. Available at <https://www.hhs.gov/opioids/>

⁶ CDS Connect Contract Year 1 Final Report, <https://cds.ahrq.gov/cdsconnect/reports>.

⁷ Osheroff J.A., Pifer E.A. Teich J.M. et. al. *Improving Outcomes with Clinical Decision Support: An Implementer's Guide*, 2 Ed. Danvers, MA: HIMSS Publishing, Taylor & Francis Group/CRC Press, 2012.

opportunity to ensure proper translation of the evidence, leading to CDC approval to cite the guideline as the evidence-based source.

Next, applying the 5 Rights, the multidisciplinary MITRE team developed more than a dozen different CDS approaches to support patients and providers when managing pain. A small sample of the approaches include:

- A checklist of CDC-recommended items to consider prior to ordering an opioid medication
- A calculator or order set to support opioid tapering
- A documentation template to facilitate pain and risk assessment details and scores
- A summary dashboard to display clinical concepts relevant to pain management (i.e., a pain management summary)
- An alert and/or order set to consider naloxone if risk factors for opioid-related harm are identified in the patient record

The CDS Connect team socialized the list of CDS approaches with potential pilot partners to solicit feedback and provide an opportunity for the sites to select an approach that they felt most beneficial to their organization and clinicians. Consistently, the clinical and health IT organizations selected the “Pain Management Summary” CDS as the preferred approach (formally titled *Factors to Consider When Managing Chronic Pain: A Pain Management Summary*).

The CDS Summary approach likely resonated with them because the scope and complexity of data required by the care team (patient, caregivers, and clinicians) to relieve pain and improve health and wellness is staggering. Relevant data are often fragmented and difficult to find and interpret. Successful treatment of chronic pain requires consideration of numerous aspects of the patient’s health history, previous treatments, individual behavior, physical environment, and social circumstances. An accurate, well-designed, and context-specific pain management summary can potentially save time, improve clinical accuracy, and reduce potential errors in both outpatient and inpatient care.⁸

2.1.2 Semi-Structured Representation of the Pain Management Summary CDS

⁸ Thomas SM, Overhage JM, Warvel J, McDonald C.J. (2001). A Comparison of a Printed Patient Summary Document with its Electronic Equivalent: Early Results. 1067-5027/01 © 2001 AMIA, Inc.

Boxwala, et al.⁹ developed a multi-layered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts. The framework defines four “layers” of representation:

1. **Narrative** text created by a guideline or clinical quality measure (CQM) developer (e.g., the recommendation statement described as a sentence).
2. **Semi-structured** text that describes the recommendation logic for implementation as CDS, often created by clinical subject matter experts (SMEs). It serves as a common understanding of the clinical intent as the artifact is translated into a fully structured format by software engineers.
3. **Structured** code that is interpretable by a computer and includes data elements, value sets, and coded logic.
4. **Executable** code that is interpretable by a CDS system at a local level. This code will vary for each site.

After identifying the evidence-based source (the CDC guideline *narrative text*) and determining the “5 Rights” (e.g., a summary of relevant patient data presented to the clinician), MITRE created a *semi-structured* representation of the CDS to add structure to the evidence and serve as a vehicle for communication between clinical SMEs and knowledge engineers. In collaboration with the CDC, CDS Connect work group members, OCHIN clinicians, CDS experts, and system engineers, the semi-structured representation Pain Management Summary CDS was finalized. Representations of the inclusion and exclusion logic are listed in Table 2, and the intervention logic (i.e., pain management summary content) is listed in Table 3.

⁹ Boxwala, AA, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc* 2011(18) i132-i139.

Table 2. Final Semi-Structured Inclusion and Exclusion Logic

Inclusions
<p>Age >=18 years</p> <p>AND</p> <p>OR Conditions associated with chronic pain (<i>confirmed, active or recurring status, onset date, asserted date, abatement date</i>)</p> <p>OR Opioid pain medication</p> <p style="padding-left: 40px;"><i>Orders (date, active, completed, or stopped within past 180 days)</i></p> <p style="padding-left: 40px;"><i>Statements (date, active, or completed within past 180 days)</i></p> <p>OR Adjuvant analgesic medication</p> <p style="padding-left: 40px;"><i>Orders (date, active, completed, or stopped within past 180 days)</i></p> <p style="padding-left: 40px;"><i>Statements (date, active, or completed within past 180 days)</i></p>
Exclusions
None

Table 3. Final Semi-Structured CDS Intervention logic

CDS Intervention
POPULATE Pain Management Summary
<p><u>Pertinent Medical History</u> (unrestricted lookback):</p> <p>Conditions associated with chronic pain (<i>confirmed, active or recurring status, onset date, asserted date, abatement date</i>)</p> <p>Risk factors for opioid-related harm</p> <p style="padding-left: 40px;"><i>Risk Conditions (represented by a union of value sets) - (confirmed, active or recurring status, onset date, asserted date, abatement date)</i></p> <p style="padding-left: 40px;"><i>Encounter Risk Diagnosis (represented by a union of value sets) - (name, visit date, onset date, abatement date, and recorded date)</i></p> <p style="padding-left: 40px;"><i>Pregnancy Observation in the past 42 weeks</i></p> <p style="padding-left: 40px;"><i>Age >=65 years</i></p>

CDS Intervention
<p><u>Pain Assessments</u> (lookback of 2 years):</p> <p>Wong-Baker FACES Assessment (<i>score, interpretation, date</i>)</p> <p>PEG Assessment (<i>question response and total score, interpretation, date</i>)</p> <p>STarT Back Screening Tool (<i>total score, interpretation, date</i>)</p>
<p><u>Historical Treatments</u> (lookback of 2 years for all except stool softeners, which is 6 months):</p> <p>Opioid pain medication</p> <p><i>Orders (date, active, completed, or stopped)</i></p> <p><i>Statements (date, active, or completed)</i></p> <p>Non-opioid pain medication</p> <p><i>Orders (date, active, completed, or stopped)</i></p> <p><i>Statements (date, active, or completed)</i></p> <p>Non-pharmacologic treatment</p> <p><i>Orders (date, accepted, in progress, or completed)</i></p> <p><i>Referrals (date)</i></p> <p>Stool softener and laxative</p> <p><i>Orders (date, active, completed, or stopped)</i></p> <p><i>Statements (date, active, or completed)</i></p>
<p><u>Risk Considerations:</u></p> <p>MME calculation (<i>most recent, verified, value [as quantity], date in past 6 months</i>)</p> <p>Urine drug screen (<i>verified, result, interpretation, date in past 1 year</i>)</p> <p>Benzodiazepine medication</p> <p><i>Orders (date, active, completed, or stopped in the past 2 years)</i></p> <p><i>Statements (date, active, or completed in the past 2 years)</i></p> <p>Naloxone medication</p> <p><i>Orders (date, active, completed, or stopped)</i></p> <p><i>Statements (date, active, or completed)</i></p> <p>Risk assessments relevant to pain management (<i>represented by a value set</i>) - (<i>total score, range, interpretation, date in past year</i>)</p> <p><i>Verified “single question r/t alcohol use” Observation</i></p> <p><i>Verified “single question r/t drug use” Observation</i></p>

CDS Intervention
DISPLAY link to the CDC Guideline for Opioid Prescribing for Chronic Pain
DISPLAY Notice header: “TAKE NOTICE: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment .”

2.1.3 Structured Representation of the Pain Management Summary CDS

Next, MITRE developed the *structured* representation of the CDS (i.e., code that is interpretable by a computer, including data elements, value sets, and logic). The artifact was authored using: 1) HL7 CQL, which enables point-to-point sharing of executable clinical knowledge as human-readable language; and 2) the FHIR DSTU2 data model, which is built on ubiquitous proven web technologies and is supported by many vendor systems.

Clinical SMEs evaluated value sets hosted in the NLM Value Set Authority Center (VSAC) and in a [CDC Opioid Prescribing Support CDS Implementation Guide](#) to determine if available value set expressions were aligned with the Pain Management Summary use case. When indicated, MITRE developed new value sets to properly convey a required concept, and SMEs validated the new definition. MITRE clinicians also collaborated with a Logical Object Identifier Names and Codes (LOINC) representative to apply for LOINC code assignments to two pain assessment tools expressed in the Summary. Since the new codes are not anticipated to be available until the December LOINC release, MITRE used “local” codes from OCHIN’s system to represent the assessment components. Subsequent implementers might choose to replace the local codes with LOINC codes, once available.

Ultimately, individual standard codes, local codes, or value sets were selected to represent each data element referenced in the logic. The declaration of value sets, codes, and concepts in the CQL code complies with [CQL specifications](#) and standards. A Universal Resource Locator for each VSAC-hosted value set is provided in a comment above each value set declaration in the CQL code to ensure accessibility to the component codes.

The CDS Connect team created a CQL Library in Year 1 to capitalize on capabilities of the CQL standard after numerous CDS logic patterns were identified. The team updated the library this year (i.e., CDS_Connect_Commons_for_FHIRv102), which enabled developers to reuse common functions, reducing repetitiveness and improving consistency across the artifact itself, as well as across different artifacts entirely. The library uses the FHIR DSTU2

data model and implements common functions using attributes available in the stated version.

For organizational purposes, MITRE divided the artifact logic into three sections. The first section calculates the population of patients who meet the inclusion criteria for the CDS artifact. MITRE-developed libraries perform most of the required filtering, sorting, and conversion of data elements. CQL logic in this section closely reflects the logic described in the “inclusion” and “exclusion” sections of the *semi-structured* representation.

The second section of the CQL logic gathers all the pertinent patient record information and formats it for display within the Pain Management Summary described in the next section of this paper. The final section of the CQL logic organizes this formatted information into sections required by the Pain Management Summary.

To provide additional transparency to individuals considering implementation, MITRE engineers annotated the CQL code to provide contextual decisions and highlight parameters that might be adjusted by each unique end user.

2.1.4 Executable Representation of the Pain Management Summary CDS

The Pain Management Summary CDS displays relevant data to inform the decision-making process when managing a patient’s pain. MITRE developed CQL logic to programmatically collect and organize the relevant data, but other technologies must be used to present it to clinicians and patients. MITRE and OCHIN considered several approaches for displaying the Summary in OCHIN’s Epic system, including SMART on FHIR,¹⁰ CDS Hooks,¹¹ and proprietary Epic API¹² integrations.

MITRE and OCHIN chose to implement the display of the Pain Management Summary as a SMART on FHIR application. SMART on FHIR was chosen for its standards-based approach, allowing for integration across a variety of EHRs, as well as for its flexibility in application implementation technologies and UI design.

The Pain Management Summary application presents a clean, modern user interface with data organized in a consistent way (Figure 3). The patient name, gender, and age are prominently displayed at the top of the page along with an overall count of relevant entries

¹⁰ <https://smarthealthit.org/>

¹¹ <https://cds-hooks.org/>

¹² <https://open.epic.com/Clinical/Other>

and flags. Flags are used throughout the application to signal that special attention should be paid to specific entries (or to a lack of entries in some cases).

The Pain Management Summary divides the relevant data into four major sections: Pertinent Medical History, Pain Assessments, Historical Pain-related Treatments, and Risk Considerations. Each section contains entries (and potentially flags) related to the section topic. Users can navigate through the application by using the table of contents on the left-hand side or by scrolling up and down.

CDS Connect Fuller Jackson 64 YRS MALE 22 Total Entries 8 Total Flags

Factors to Consider in Managing Chronic Pain

TAKE NOTICE: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment.

Pertinent Medical History (3)

Conditions Associated with Chronic Pain

Name	Status	Start	End	Recorded
Fibromyalgia (disorder)	active	2012-Apr-05 (age 58)		2012-Apr-05

Risk Factors for Opioid-related Harms

Name	Status	Start	End	Recorded
Agoraphobia with panic attacks (disorder)	active	2014-Sep-01 (age 60)		2015-Feb-12

Visit

Name	Visit
Suicide attempt, initial encounter	2015-Feb-01 (age 60) - ongoing

Figure 4. The Pain Management Summary user interface

MITRE developed the Pain Management Summary application using several open source technologies. The SMART on FHIR JavaScript client library¹³ provides support for responding to application launches, handling user authorization, and performing FHIR queries against the EHR. The CQL Execution library¹⁴ provides the core functionality of the application, interpreting the Pain Management Summary CQL logic to filter, aggregate, and organize the relevant data to be presented to the user. Finally, the React¹⁵ framework uses the data in the CQL results to render the web-based user interface and allow for user interaction with the Summary.

¹³ <https://github.com/smart-on-fhir/client-js>

¹⁴ <https://github.com/cqframework/cql-execution/>

¹⁵ <https://reactjs.org/>

The Pain Management Summary application compiles to standard Hyper Text Markup Language (HTML), JavaScript, and Cascading Style Sheets (CSS). As such, it can be deployed on any modern web server such as Apache Hypertext Transfer Protocol (HTTP) Server¹⁶ or Nginx.¹⁷ In addition to developing automated unit tests, the MITRE team manually tested the Pain Management Summary application via the public SMART and Epic Smart App Launchers.^{18,19} As part of this effort, a series of synthetic patients were created to exercise different aspects of the application. This allowed the SMART on FHIR interaction to be validated before integration at OCHIN.

Prior to the pilot, MITRE demonstrated the Pain Management Summary application to several pain management experts, clinicians, and stakeholders. Feedback has generally been very positive, with one pain management expert proclaiming it to be the best implementation he had observed of the CDC's *Guideline for Prescribing Opioids for Chronic Pain*. Pilot feedback was also positive, but concerns were raised about application performance (i.e., latency) and potential data integration issues related to site-specific customization.

MITRE and AHRQ plan to release the Pain Management Summary SMART on FHIR application as open source software using the Apache 2.0 license in September 2018. Potential enhancements to the Pain Management Summary (whether performed by MITRE or others) might include performance optimizations, addition of other related concepts, built-in morphine milligram equivalents (MME) calculation, and/or integration with prescription drug monitoring programs (PDMP).

2.1.5 Artifact Testing and Quality Review

Unit tests using Mocha and Chai test frameworks were written to ensure CQL code correctly calculated the intended population logic and summary data. The tests used synthetic patient data to validate the reliability and validity of CQL code based on how each test case evaluated against defined logic. Tests were performed each time a change was made to CQL specifications, to ensure the updated code performed as expected.

Prior to public release, the Artifact Development Team performed a quality review of each artifact to ensure that the *semi-structured* and *structured* CDS representations aligned with

¹⁶ <https://httpd.apache.org/>

¹⁷ <https://www.nginx.com/>

¹⁸ <http://launch.smarthealthit.org/index.html>

¹⁹ <https://open.epic.com/Launchpad/Oauth2Sso>

the intent of the CDC guideline. Reviews included evaluation of value set selections, clinical and verification status definitions, lookback periods, parameters, lab values, and alternative expressions of a clinical concept. Items put forward by the Work Group and OCHIN clinicians were double checked, as well as each item that made the CDS expression deterministic and computable. CQL code annotations were added, when indicated, to ensure contextual decisions were provided in key sections of CQL code. Items identified for revision were re-reviewed by the full multidisciplinary team. Once validated by all members of the Artifact Development Team, the artifact was approved for upload to the Repository.

2.1.6 Artifact Enhancements and Pilot Implementation

MITRE partnered with OCHIN and one of their member health centers to pilot the Pain Management Summary CDS in a live clinical setting. A *Pilot Final Report* outlining all aspects of the pilot (e.g., the implementation plan, technical integration process, quantitative and qualitative findings, and lessons learned) is available as an attachment to the Summary artifact in the Repository. Enhancements made to the CDS expression during the pilot process, informed by how data are captured and stored in OCHIN's system, and integration and testing results are outlined in the *CDS Artifact Enhancement based on Pilot Implementation* document (also available within the Summary artifact on the Repository).

2.1.7 Challenges Encountered During Artifact Development

Artifact development is complex, requiring significant expertise and research to create reliable and accurate CDS. It is best accomplished with a multidisciplinary team comprising clinical SMEs, end users, informaticists, software engineers, and even patients. Challenges often arise during the development process, forcing the development team to make informed decisions on how to best overcome the identified issues.

The Artifact Development Team encountered the following challenges during development of the Pain Management Summary CDS:

- **Ensuring alignment to an evidence-based source.** Usually this is not a large challenge—especially when deriving CDS directly from one recommendation statement, since the directive is clear (e.g., all patients 40-75 years old who have suffered a heart attack should be discharged from an inpatient facility on a beta-blocker medication). However, if the CDS is not a direct translation of the evidence (i.e., it is *informed* by the evidence), as the Pain Management Summary CDS is, it is easy to diverge from the intent. Trouble can arise when developers pick and choose

where they want to align (e.g., opioid prescribing guidance for chronic pain) and where they do not (e.g., provide the guidance for individuals of *all* ages as opposed to only individuals ≥ 18 years old as outlined in the CDC guideline). Divergence from the guideline risks the validity and evidence base of the CDS intervention. Developers should clearly outline their translation decisions and caution end users regarding when and where they diverge from evidence that they are citing. MITRE collaborated with the program office responsible for the CDC guideline to validate the CDS expression and ensure key components (e.g., an individual's age) aligned with the authored guideline.

- **Navigating intellectual property constraints.** Published scientific knowledge usually has intellectual property (IP) restrictions outlining how the work can be used, copied, shared, etc. Since evidence-based CDS is often derived from published knowledge, the developer must gain IP approval to express the author's work as CDS. MITRE initially hoped to include the published interpretation of pain assessment scores in the CQL code (e.g., a score of "2" is interpreted as "hurts a little bit"); however, the pilot timeline could not afford a delay for IP review and approval. Instead, MITRE chose to provide the available range of responses instead of the interpretation (e.g., a score of "2" on a scale of "0-10"), to provide a contextual understanding of the score. This approach did not require IP approval. Awareness of and compliance with legal restrictions should always be considered during CDS development.
- **Availability of standard codes.** Standards-based, interoperable CDS is dependent upon the availability of standardized codes to express the clinical data elements used in the logic. Terminologies such as LOINC provide a wealth of codes for CDS developers to use in their CDS expression. If codes are not available for a specific concept, developers are forced to use local codes to express the concept, lessening the interoperability of the final coded artifact. MITRE encountered a gap in the availability of standard codes to represent pain and risk assessments, MME amount, and PDMP access during CDS development. The team notified a LOINC representative of several of these gaps and applied for 19 new LOINC codes to represent elements from two prominent pain assessments (PEG and STarT Back). CDS and eCQM developers are encouraged to notify terminology stewards of gaps, so efforts can be made to assign needed codes. The MITRE team used local codes as placeholders until standard codes are assigned.
- **Identifying appropriate existing value sets available in VSAC and other internet locations to encode clinical concepts.** This process is challenging and resource-

intensive for numerous reasons: many value sets are missing metadata (requiring reverse engineering of the content to understand appropriateness for reuse), there is no tooling available to compare and reconcile value set content, and there is no mechanism to determine which value sets are deprecated and should no longer be used. In addition, search efforts can be hit or miss in identifying value sets posted outside of value set databases (e.g., a FHIR implementation guide), causing potential re-expression of identical clinical concepts. Although the clinical team successfully identified one value set outside of VSAC and six value sets within VSAC for the Summary, 13 additional value sets were created to enable the CDS.

- **Identifying evidence of procedures and treatments in a primary care EHR.** Procedures and treatments rarely occur in a primary care setting. Therefore, evidence of a treatment being “performed” or “completed” is usually not available in their EHR. Alternative approaches, such as looking at orders or referrals can help identify *some* evidence of these concepts, but limitations exist with this approach also (i.e., some treatments do not require an order or referral, such as “stretching” or “exercise”). CDS developers and implementers must take caution when trying to evaluate captured data for evidence of procedures and clearly convey CDS limitations to the end users.
- **Identifying patient goals and reasoning over goal status.** Consideration of patient goals is paramount to pain management decision making; however, this information is rarely recorded in a structured field, jeopardizing the effectiveness of CDS that tries to reason over this data. Factors influencing the lack of data may include a deficiency in readily available and user-friendly documentation templates, clinical workflow limitations, and limited time during a patient encounter. EHR enhancements and quality improvement efforts may one day improve the capture of this information.
- **Accurate capture of the date of diagnosis.** EHRs consistently capture the date that a new diagnosis is entered in the system. Often, that date is displayed and stored as the “onset date,” which *may* be a misrepresentation of the date. This is a significant limitation for CDS logic that evaluates the “onset date” of a Condition to provide guidance on an evidence-based treatment. Caution is required when evaluating this concept. Including the “asserted date” in the CDS provides context to the date presented as the “onset date.”

2.2 Additional Artifacts Developed in Year 2

During outreach efforts described in [Section 1.2](#) of this report, MITRE identified opportunities to collaborate with external stakeholders to expand the impact of the project through the development of two additional CDS artifacts.

2.2.1 [Occupational Factors Impacting Diabetes](#)

The National Institute for Occupational Safety and Health (NIOSH), a research agency within the CDC that is focused on the study of worker safety and health, recently released a new evidence-based knowledge resource titled *Using Electronic Health Records and Clinical Decision Support to Provide Guidance on Occupational Factors which Impact Diabetes: A Final Knowledge Resource Report*.²⁰ NIOSH identified the value of demonstrating their new knowledge resource in the HIMSS Interoperability Showcase (IS) and became early organizers of a “use case” to exhibit Value-Based Care. The use case assembled a cross-section of commercial, clinical, and Government organizations to showcase interoperability-enabled value-based care to support a fictitious individual whose profession and work conditions were impacting his ability to effectively manage his diabetes. Through ongoing outreach and collaboration with individuals within the CDC, as outlined in the [Task Management](#) section of this report, NIOSH became aware of the CDS Connect project and MITRE’s expertise in the CDS domain and invited MITRE to participate in the Showcase.

MITRE was selected to kick off the exhibition by demonstrating the utility of the CDS Connect Repository to host and share standards-based interoperable CDS that can be downloaded and integrated into an EHR (GE Centricity) in a clinical organization (an AllianceChicago network health center). The use case went on to demonstrate a referral that was forwarded to a nutritionist, and so on, as depicted in Figure 5.

²⁰ National Institute for Occupational Safety and Health, Association of Occupational and Environmental, Diabetes subject matter expert group. December 4, 2015. Using Electronic Health Records and Clinical Decision Support to Provide Guidance on Occupational Factors Which Impact Diabetes: A Final Knowledge Resource Report. Produced under CDC/NIOSH contract 212-2014-M-59011.

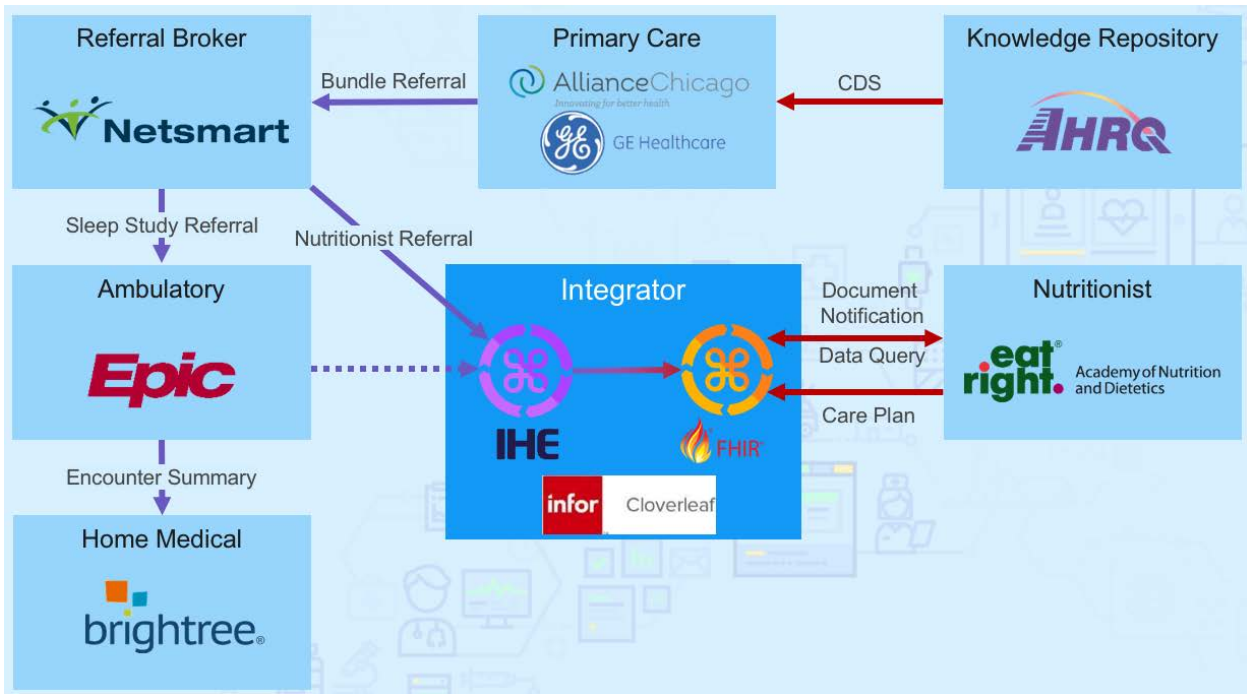


Figure 5. HIMSS IS: Value Based Care Use Case and Participating Organizations

Although the original plan enlisted a NIOSH contractor to develop the CDS for the HIMSS demonstration, the HIMSS timeline did not align with the contractor's CDS development timeline. As a result, MITRE created a simple structured artifact for the Showcase titled *Occupational Factors Impacting Diabetes*. The artifact presents educational materials to practitioners and patients regarding work schedules and conditions that could put a diabetic patient at compromise (i.e., shift work, temperature extremes, heavy physical activity, difficulty taking medications or eating regularly, and safety sensitive activities). The "[Occupational Factors](#)" CDS artifact is posted on the Repository as "draft" (i.e., work under development) and "experimental" (i.e., developed for demonstration or educational purposes; not ready for clinical use), since it was not tested in a clinical environment. NIOSH contractors may contribute a more mature, fully-tested representation of the knowledge as a structured artifact at a later date.

2.2.2 [CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk](#)

This artifact calculates a baseline 10-year arteriosclerotic cardiovascular disease (ASCVD) risk score to support primary prevention of ASCVD (prior to initiation of preventive therapies). It uses the 2013 American College of Cardiology/American Heart Association pooled cohort equation to calculate the risk of developing a first time “hard” ASCVD event, defined as: nonfatal myocardial infarction, coronary heart disease, death, nonfatal stroke, or fatal stroke.

In Year 1 of the CDS Connect project, MITRE developed a semi-structured (i.e., human-readable) representation of this equation, but was unable to express the predictive risk calculator as coded logic due to a delay in gaining IP clearance. Through continued engagement with stakeholders at CMS and the Million Hearts® initiative, CDS Connect received IP approval to move forward with developing the coded representation of the baseline calculation in Year 2 (Y2) of the project. The updated CQL-expressed artifact identifies the specified data components for the equation in the patient record (displayed in Figure 6) and calculates the patient’s risk of developing ASCVD in the next 10 years.

Semi-Structured Logic	
Inclusion	Age >=40 and <=79 years
Exclusions	None
Intervention	DISPLAY segment of the Longitudinal ASCVD Risk Assessment Tool that provides the ability to input the following data concepts: 1) Age 2) Gender (M/F) 3) Race (White/AfricanAmerican/Other) 4) Total Cholesterol - MOST RECENT within past 6 years (measured as mg/dL). Allowable result range: 130-320 mg/dL 5) HDL Cholesterol - MOST RECENT within past 6 years (measured as mg/dL). Allowable result range: 20-100 mg/dL 6) Systolic Blood Pressure - MOST RECENT within past 6 years (measured as mmHg). Allowable result range: 90-200 mmHg 7) Treated for high blood pressure - (Y/N) determined by a diagnosis of Hypertension AND an active anti-hypertensive medication 8) Diabetes (Y/N) 9) Current Smoker (within past year) - (Y/N) - MOST RECENT within the past year
Intervention	POPULATE fields in CMS's Million Hearts Model Longitudinal Risk Tool
Intervention	CALCULATE risk score
Intervention	DISPLAY risk score

Figure 6. Semi-structured Representation of the Longitudinal ASCVD Risk Tool

The structured [Longitudinal ASCVD Risk Assessment Tool](#) artifact is now available on the CDS Connect Repository. It may be of significant interest to health IT vendors and clinical organizations that do not have this equation embedded in their systems.

Task 3. Pilot PCOR CDS Artifacts

The CDS Connect project included the execution of a feasibility pilot to provide a real-world approach with end-user experience and feedback to the development and implementation of

clinical decision support. The scope of the pilot included engaging with a designated clinical site for the implementation of the Pain Management Summary CDS and subsequent use by designated clinical providers for a multiweek intervention period. Additional pilot details are available in the *Pilot Final Report*, including the implementation plan, technical integration process, quantitative and qualitative findings, and lessons learned.

In preparation for the pilot, the CDS Connect project team created a CDS Connect Pilot Plan outlining the scope, goals, and outcome success factors of the pilot; key activities to accomplish to ensure pilot success; and definition of the optimal pilot site characteristics and pilot site selection process.

The primary goals of the pilot included: 1) developing and demonstrating the feasibility of a self-service CDS environment that encourages development, implementation, evaluation, and dissemination of PCOR-based CDS; 2) providing evidence-based and value-add resources for inclusion in the CDS Connect Repository to be used by clinical organizations interested in implementing CDS artifacts; 3) informing and enhancing the specification of the piloted artifact based on integration test results and implementation findings; and 4) gaining an understanding of pilot stakeholder views as they experience pilot activities.

3.1. Pilot Site Characteristics and Selection.

For the pilot, MITRE sought a collaborator with both technical readiness and a suitable clinical environment to pilot the Pain Management Summary CDS. Key factors that influenced selection included identifying a pilot site that was invested in supporting their providers' decision-making process via CDS, as well as ensuring that the clinical domain (i.e., chronic, nonmalignant pain management and proper opioid prescribing) resonated with the organization. Additional preferred characteristics included identifying an ambulatory practice with clinicians representing internal and family medicine; ensuring the required data could be captured in the site's EHR; the availability and support of clinical, operational, and technical staff, including the technical capability to implement the CDS; and verifying that the site has the organizational commitment and operational resources to meet pilot needs before, during, and after implementation.

MITRE evaluated several potential pilot partners and, in collaboration with AHRQ, determined that OCHIN met all defined pilot criteria. OCHIN is one of the largest health information and innovation networks in the United States, and partners with Epic and NextGen to provide EHR products to their member organizations. Members consist of

inpatient and outpatient facilities that receive Federal assistance to provide care to underserved populations. OCHIN was awarded a subcontract through the MITRE Corporation for the performance period of March 1, 2018, through August 31, 2018.

Given the research and evaluation nature of the work and the project's goal to provide both specific and generalizable knowledge to a broad community of stakeholders, the CDS Connect project team engaged in the Institutional Review Board (IRB) process, to ensure compliance with applicable human subject protection policies. The MITRE IRB provided their approval, granting the project exempt status.

3.2. Pilot Implementation Planning

MITRE drafted an initial pilot work plan to establish the proposed timeline and implementation details as well as the critical path activities and risks. Once the pilot subcontract was finalized, a 2-day virtual kick-off meeting was conducted with the key OCHIN and MITRE team members to review the pilot scope and work plan, review and refine the clinical aspects of the Pain Management Summary CDS and begin discussing the technical integration of the CDS within the OCHIN EHR, as well as other related activities.

The MITRE team also evaluated how well the pilot objectives were met. Qualitative data were collected through two focus group meetings at the end of the pilot with the pilot site clinicians. In addition, an Analytic Plan was created in collaboration with OCHIN to provide quantitative data at pre-determined intervals during the pilot period (e.g., pre-pilot site implementation, during the pilot, and after the pilot conclusion).

To maintain ongoing situational awareness and communication, CDS Connect project leadership held weekly technical and management calls with the OCHIN project leaders from mid-April through August 2018. Throughout the pilot period of performance, OCHIN and MITRE leadership and key resources were readily available to address questions or issues as needed.

OCHIN achieved agreement from one of their member organizations, a nonprofit community health center in California, to serve as the pilot clinical site. The MITRE team developed a training plan along with training materials to inform and educate the pilot site about the pilot objectives, as well as the Pain Management Summary, and led the remote training for the pilot site clinicians.

3.3. Pilot Site Technical Integration

Integration of the Pain Management Summary CDS within the OCHIN Epic EHR required both organizations' technical teams to develop or customize software to present the Summary data to clinicians and patients. MITRE and OCHIN considered different methods for integration and determined that using a SMART on FHIR application was the best approach. SMART on FHIR provided a standards-based, plugin framework for custom apps and was supported by Epic. OCHIN elected to invoke the SMART on FHIR application when a clinician clicks on a "Pain Summary Information" link found within a specific patient record in the EHR.

The integration of the SMART on FHIR app required a significant level of coding and mapping from OCHIN. Modifications were necessary to support Epic's specific requirements and limitations for the SMART on FHIR platform, such as development of a proxy API to handle FHIR queries not supported by Epic. In addition, a significant amount of mapping was required to ensure capture of the appropriate data. Throughout the course of development and implementation of the pilot integration, the CDS Connect and OCHIN teams met to discuss requirements, architecture, technical approach, and outstanding issues.

3.4 Analysis of the Pain Management Summary

MITRE tested the Pain Management Summary CDS and SMART on FHIR app throughout the development cycle, using a comprehensive set of test cases and synthetic patient data. After integration of the Pain Management Summary app in the OCHIN environment was completed, OCHIN quality assurance personnel began formal testing. MITRE contributed to the testing by providing sample data to test each area within the Pain Management Summary as well as sample testing scenarios. In addition, MITRE conducted qualitative and quantitative analysis.

3.4.1 Qualitative and Quantitative Pilot Findings

At the completion of the pilot, MITRE conducted two virtual focus groups with the OCHIN clinicians who participated in the pilot to obtain qualitative feedback. Questions and discussion focused on the clinicians' experience with the CDS, their thoughts on the clinical and patient utility of the CDS, and insight into the incentives and barriers faced with the CDS. Generally, the clinicians felt that the Summary was a useful tool and included beneficial information to help guide the care process. They praised the user interface and remarked that their prior workflow to locate similar information required accessing multiple tools and tabs. They mentioned several barriers to using the Summary, including a lag time in display of the Summary once the link is selected. Their primary recommendations

included integration with the PDMP and optimization of the performance to reduce the lag time for the Summary display.

Reports created by OCHIN at the pilot conclusion provided quantitative data from both the Epic EHR as well the SMART on FHIR app. The MITRE team performed further analysis with the following high-level findings:

1. During the 8-week clinical pilot, clinicians clicked on the link for the Pain Management Summary a total of 85 times, or an average of 10.6 times each week.
2. Clinical data expressed in the Pain Management Summary CDS was available in a structured format, except for “responses” and “scores” related to two multi-dimensional assessments that are not used by clinicians at the pilot site.

The pilot achieved the goal of developing, refining, and verifying that the MITRE-developed Pain Management Summary performed as expected in a live clinical setting with successful integration with the EHR, validation of the Summary design and content, and agreement by the pilot site clinicians that the information provided was valuable and contributed to patient care. The feedback and experiences of the OCHIN pilot team provided extremely valuable input to the CDS Connect project. MITRE is tremendously appreciative of OCHIN’s partnership and collaboration on this effort.

Task 4. Develop Prototype Tools for Sharing PCOR CDS Artifacts

A main goal of the CDS Connect project is to enable the sharing of CDS based on PCOR. This is brought about in various ways through the different tasks described in this final report. The work described in this section focuses on providing prototype software tools that enable sharing and/or execution of artifacts that represent the CDS evidence and logic.

The CDS Connect Repository is just one such example of a prototype software tool; others have been developed to support specific use cases, most notably the CDS Connect pilot. Feedback from the CDS Connect Work Group helped to determine what prototype tools were developed and what capabilities they provide. The tools described in this section were reviewed with the working group numerous times during Y2 of the CDS Connect project.

4.1 Production Level CDS Repository

MITRE developed an alpha and a beta version of the CDS Connect Repository during the first year of CDS Connect. During Y2, MITRE released and subsequently updated a production version of the Repository. The [CDS Connect Repository](#) serves as an online resource for contributing, editing, publishing, viewing, and storing CDS artifacts. While the beta version of the Repository provided the basic capabilities to satisfy these requirements during the first year, MITRE made numerous refinements during Y2. This section describes the various functionalities added to the Repository during Y2, both before and after release of the production version.

4.1.1 Repository Enhancements

This section describes enhancements made to the Repository after the production version was released. They illustrate the continued refinement and evolution of the Repository's capabilities and functionalities.

1. **Copyright Complaint Form:** The Digital Millennium Copyright Act (DMCA) creates a safe harbor for online service providers who are accused of copyright infringement when their users post or share infringing materials. A service provider invokes the safe harbor by complying with a notice-and-takedown process whereby the copyright owner can ask the provider to remove the infringing content. MITRE developed a Copyright Complaint Form, compliant with the DMCA notice-and-takedown process, which allows users to report copyright infringement on the CDS Connect site. The

form is accessible from the Frequently Asked Questions (FAQ) tab in the Repository and from a link within each published CDS Connect artifact. The form consists of six fields users must complete as part of their submission: Name, Email Address, Telephone, Address, Claimed Material, and a Written Assertion of Good Faith. This form was added in Y2 and is tested regularly to ensure it is correctly functioning.

2. **Topics:** New artifacts spanning varied domains prompted MITRE to implement Topics as a mechanism for organizing CDS artifacts on the Repository. Topics and topic pages were added to the Repository in advance of the demonstration at the HIMSS 2018 conference.²¹ Currently, CDS artifacts are presented to viewers organized by topic area (e.g., Opioids and Pain Management, Immunization). However, topic areas must be manually added to the Repository, and the corresponding view of all artifacts must be manually updated. While this approach works for small numbers of artifacts in a prototype system, it is not sustainable nor scalable. Going forward, a more automated approach will be needed to manage topics and the presentation of artifacts on the Repository.
3. **ForeSee Survey:** MITRE implemented and deployed the ForeSee customer satisfaction survey to the live CDS Connect Repository. MITRE encountered several technical difficulties that were eventually overcome during the deployment of the survey. Successful resolution involved appropriately managing configuration settings on the development, staging, and production (live) servers. MITRE tested and verified that the ForeSee survey was working appropriately prior to deployment.
4. **APIs:** The beta version of the Repository had a single API which was designed for use by the CDS Connect Authoring Tool. During Y2, two additional APIs were added to the Repository. The first allows artifacts formatted as FHIR Clinical Reasoning Modules to be uploaded to the Repository. The second allows artifacts formatted in the native CDS Connect format to be uploaded. Having these additional APIs will make it easier for contributors to add artifacts to the Repository. They and others will continue to be developed and refined in Year 3 of CDS Connect.
5. **Groups:** The CDS Connect Repository currently implements a publishing workflow that approximates the long-term vision. Authenticated users of CDS Connect are placed into groups based upon their organizational affiliations (users can belong to more than one group). Users in a group can develop draft (unpublished) artifacts, and users outside the group cannot see the artifacts until they are published. Figure 7

²¹ <https://www.himssconference.org/>

shows a notional depiction of this capability, as implemented using the following Drupal modules: group, gnode, and social_group.

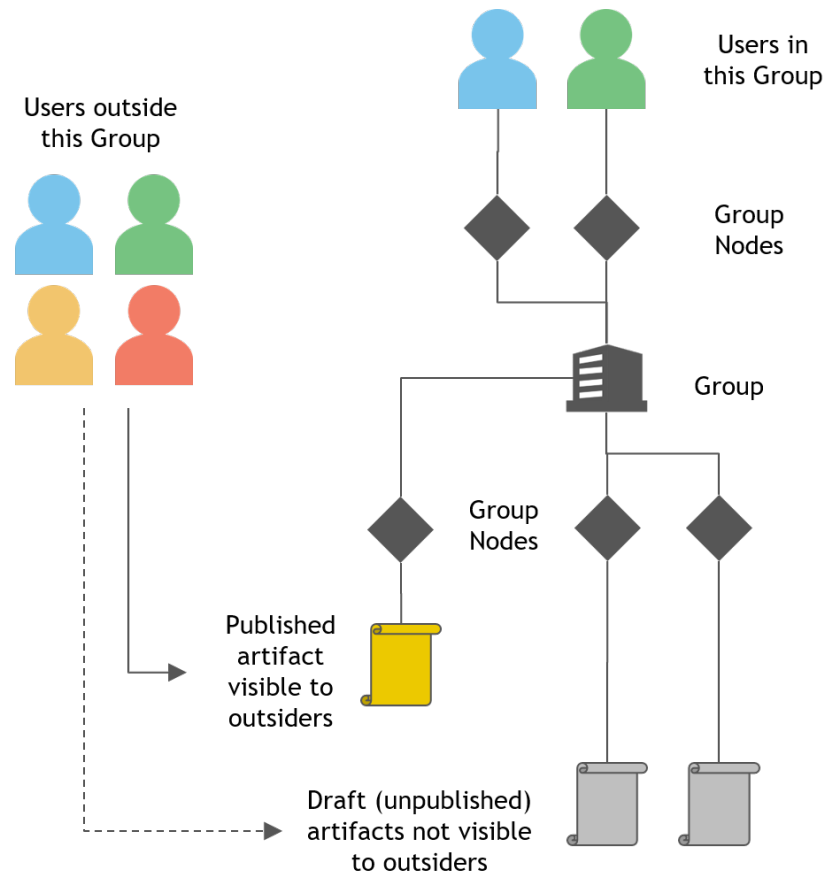


Figure 7. Notional Depiction of Groups Capability on CDS Connect

4.1.2 Repository Contributions from External Stakeholders

When the Repository was at beta-level during the first year of the project, it hosted and shared six MITRE-developed artifacts. MITRE opened the CDS Connect Repository to externally created CDS contributions after the Repository attained production-level capability. Through ongoing outreach and collaboration across the CDS community discussed in the [Stakeholder Engagement](#) section of this report, MITRE worked with individuals and organizations who communicated interest in contributing their artifacts to the Repository. The MITRE team provided an orientation on the upload process, along with a demonstration of the metadata fields, how to attach files, and how to move an artifact through the publishing process. Each contributor was given the option of uploading the work themselves or engaging with the CDS Connect clinical team to draft metadata responses for the contribution. MITRE required each contributor to attest that the artifact

was developed in compliance with the IP rights attributed to the source content and reviewed each entry before publishing it on the Repository.

Over the second year of the project, the artifact count doubled because of external CDS contributions. The new artifacts provide evidence-based interventions across an array of clinical domains for patients of all ages being cared for in a variety of clinical settings (i.e., inpatient, outpatient, emergency department). Table 4 lists the published artifacts contributed to the Repository in Y2.

Table 4. Published Artifacts That Were Contributed by External Stakeholders

Name	Topic	Contributor	Level of Representation	CDS Intervention Type
CDC Opioid Prescribing Guideline Recommendation #5	Opioids and Pain Management	CDC	Structured	Event-Condition-Action rule
CDC Opioid Prescribing Guideline Recommendation #5	Opioids and Pain Management	CDC	Structured	Event-Condition-Action rule
Healthy Weight Care Assistant	Childhood Obesity	Children’s Hospital of Philadelphia	Structured	Multi-modal
Immunization Calculation Engine	Immunization	HLN Consulting, Limited Liability Company	Structured	Multi-modal
Management of Community-Acquired Pneumonia in Adults	Pneumonia	National Organization for Research at the University of Chicago and Yale University	Semi-structured	Calculator
Refugee Health Decision Support	Refugee Care	CDC	Structured	Order Set

In the final 2 months of this PoP, MITRE expanded collaboration with individuals from the Veterans Health Administration to facilitate their contribution of structured CDS artifacts across numerous clinical domains. MITRE enhanced the Repository API to facilitate the upload of these artifacts. This effort is likely to highlight additional opportunities for enhancements to the Repository that will be realized in Year 3 of the project. MITRE anticipates that the new contributions will be published and available to the public on the Repository in Fall 2018.

4.2 Prototype Tools

During Year 2, MITRE refined and expanded the CQL execution service (also known as the “shim”) that was used to pilot the *Statin Use for the Primary Prevention of CVD in Adults*²² artifact during the base year. In January 2018, MITRE delivered the alpha version of the CQL execution service to AHRQ as the “Prototype Tools” deliverable. The alpha version provides a custom RESTful API for invoking CQL and receiving back the calculated results as JavaScript Object Notation (JSON). Using this API, clients post FHIR DSTU2²³ patient data, runtime parameter values, and desired result parameters to a registered CQL library’s endpoint. The server then executes the CQL using the provided data and parameter values and returns the results to the client. The alpha release included instructions for deployment on a Windows 2012 server as well as client scripts for testing the service.

In May 2018, MITRE delivered the beta version of the Prototype Tool, now called CQL Services. The beta version represented a major advancement, introducing support for exposing CQL logic as CDS Hooks²⁴ services. CDS Hooks is an emerging API for invoking CDS from within a clinician’s EHR workflow. It formally describes a pattern for interaction between an EHR and a CDS service, leveraging the HL7 FHIR standard and lessons learned from SMART on FHIR. CDS services exposed as CDS Hooks should be interoperable across a wide variety of EHR products as the standard continues to be adopted.

In this beta version of CQL Services, MITRE provided a mechanism for CDS implementers to configure “CQL Hooks” that define how CQL libraries should be exposed as CDS Hooks services. Through a simple JSON-formatted configuration file, implementers can specify metadata required by the CDS Hooks API, link it to a CQL library and define “cards” that are returned based on the resulting values of CQL expressions in that library.

The CQL Services includes a pre-configured CQL Hook for the *Statin Use for the Primary Prevention of CVD in Adults* artifact. The following screenshot (Figure 8) shows this CQL Hook triggered against a synthetic patient in the CDS Hooks Sandbox.²⁵

²² <https://cds.ahrq.gov/cdsconnect/artifact/statin-use-primary-prevention-cvd-adults>

²³ <https://www.hl7.org/fhir/DSTU2/index.html>

²⁴ <https://cds-hooks.org/>

²⁵ <https://sandbox.cds-hooks.org/>

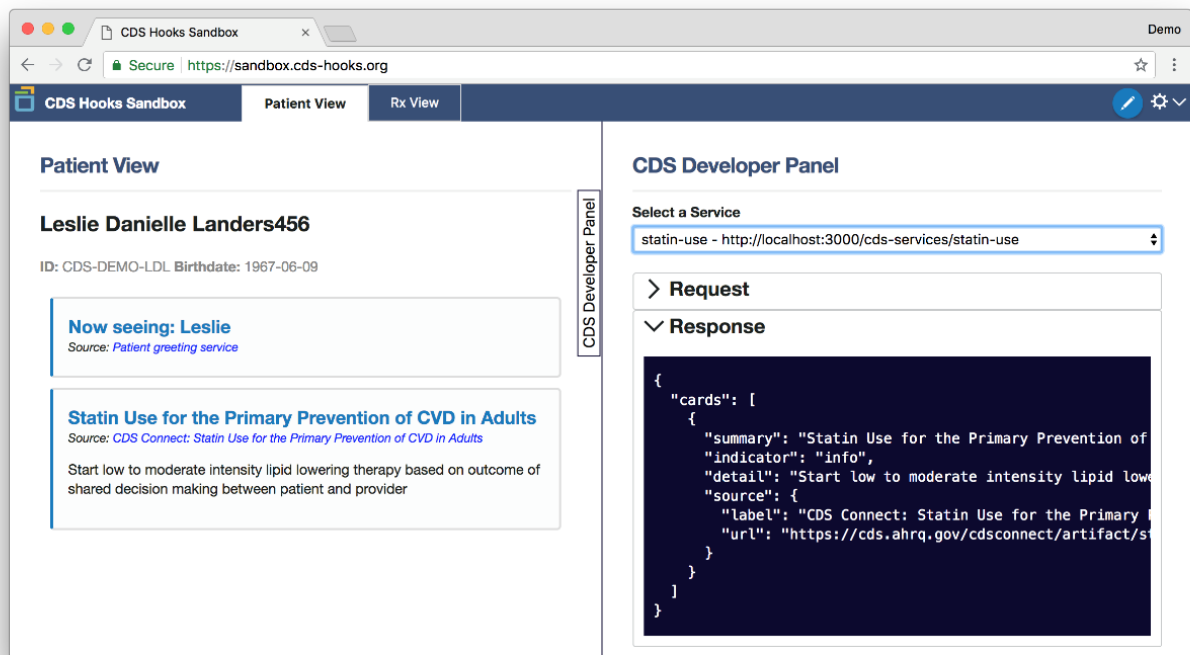


Figure 8. The CDS Hooks Sandbox Demonstrating a CQL Services CQL Hook

The CQL Hooks capability of CQL Services expects all required patient data to be sent as “prefetch” data when the service is invoked. Although the CDS Hooks specification provides a mechanism for the service to query back to the EHR for missing data, CQL Services does not currently use this approach. If there is sufficient interest, or if a future pilot requires it, this approach may be considered.

In August 2018, MITRE delivered the production version of the CQL Services prototype tools. For the production release, MITRE updated the CQL Hooks capability to conform to changes in the CDS Hooks specification after the CDS Services beta release. In addition, MITRE implemented several changes to improve security and interoperability, including enabling strict mode JavaScript, setting more secure HTTP response headers, updating dependencies with known vulnerabilities, implementing support for Cross-Origin Resource Sharing, and adding a suite of unit tests to ensure proper functionality.

MITRE and AHRQ plan to release the CDS Services prototype application as open source software using the Apache 2.0 license in September 2018. Potential enhancements to the CDS Services (whether performed by MITRE or others) might include performance optimizations, support for querying back to the EHR for additional data, and additional

flexibility in configuration. In addition, CQL Services should be updated to reflect any breaking changes in CDS Hooks when CDS Hooks version 1.0 is officially released by HL7.

Task 5. Maintain Stakeholder Working Group

A key task for the CDS Connect project was the establishment and operation of the CDS Connect Work Group. The objective of the Work Group is to advise the CDS Connect team regarding identification and prioritization of key features and capabilities for CDS Connect, leveraging the expertise of Work Group members. Members were identified through MITRE and AHRQ contacts and include representatives from key stakeholder groups such as SMEs in the domain of CDS development and tools, as well as the clinical domain of opioids and pain management, health IT experts, academic and health care leaders with a background in CDS implementation and management, and other individuals identified by MITRE, AHRQ, or other Work Group members.

MITRE was successful in standing up the Work Group at the beginning of Y2, which included the establishment of a charter that detailed goals, objectives, governance structure, and operational procedures. During the first year of performance, the Work Group was asked to self-select a Chairperson to work alongside a MITRE leader-facilitator. The same individual agreed to serve as Chairperson during Year 2. The Chairperson was responsible for co-creating a monthly agenda with MITRE leadership and co-facilitating Work Group meetings.

The primary objective of the Work Group is to solicit formal stakeholder feedback on various key aspects of CDS Connect project work, including:

- Reviewing demonstrations and documents and providing recommendations concerning the structure, capabilities, features, and operation of the CDS Connect Repository and Authoring Tool
- Providing clinical, technical, and related expertise in the domain of opioid prescribing and pain management to assist in the definition and evolution of CDS artifacts
- Offering review and feedback on specific aspects of the CDS Connect pilot

Work Group meetings were held to drive decisions to consensus, but assertions of opposing views were encouraged to ensure that all parties were properly heard and to strengthen the consensus view through subsequent discussion. The Work Group held virtual, 1.5-hour monthly meetings with additional feedback provided through follow-up emails and calls where necessary. Meeting topics included impressions from a first-time artifact contributor

on their experience, discussions, and demonstrations to solicit feedback on CDS Connect work, presentations from the Trust Framework Work Group, and updates on CDS Connect artifact development and pilot activities. MITRE also solicited feedback from Work Group members on planning and priorities for next year, including the clinical domain for CDS artifact work, as well as potential enhancements to the CDS Connect Authoring Tool and Repository.

Work Group meeting summaries and presentations are located on the [Work Group page](#) of the CDS Connect Repository.

Task 6. Hosting and Maintaining Prototype Tools

The purpose of this task is to continue hosting and maintaining the prototype tools developed during the first year of the project. User accounts that MITRE manages control access to the prototype tools; account-provisioning policies were determined during Y2. MITRE provides technical assistance to users of the PCOR CDS Repository, who may also be contributing content to the Repository. MITRE has ensured that the CDS artifacts that it has created, as well as non-MITRE CDS contributions hosted on the Repository website, support nationally recognized and interoperable data standards.

MITRE and AHRQ use LDAP to provide so-called “single sign-on” capability for both the CDS Connect Authoring Tool and the Repository. To support LDAP functionality, the Drupal-powered CDS Connect Repository leverages a contributed module that receives periodic updates. In late June, an update to the LDAP module was deployed to the production version of the Repository that unintentionally resulted in authenticated users being unable to login to the site for several days. The CDS Connect site was still accessible and viewable during this time, but authenticated users could not login to author and edit artifacts. The cause of the issue was a failure to clear a cache in the Drupal system after deploying the update. MITRE resolved the issue by clearing the cache. Because the issue arose so close to the Fourth of July holiday, it is known that actual impact to authenticated users was very minimal. A performance report did not show any attempted logins by non-MITRE users during the outage.

Drupal released numerous security patches during Y2, the open-source software framework powering the CDS Connect Repository. The most pressing and urgent patches were released

in the spring and required immediate action by the CDS Connect Repository team.^{26, 27, 28} MITRE spent significant time dealing with these security patches, particularly SA-CORE-2018-004, which necessitated upgrading much of the Drupal and associated software that powers the CDS Connect Repository. MITRE completed and deployed this major Drupal upgrade one day prior to the advertised release of the patch for SA-CORE-2018-004. Because of this, MITRE could apply the released patch within several hours of it becoming available. This and the other security patches were required but applying them did take time away from pushing out new Repository capabilities.

MITRE also spent time and effort completing numerous clean-up tasks related to major security patching over the course of the year. Generic examples of such tasks include (but are not limited to) the following: updating software components and libraries to their latest versions, resolving noncritical bugs caused by security patching, and aligning development and production code repositories. A specific example occurred after a security patch was released for the text editor used to author artifacts on the Repository. This rich text editor had been disabled during security patching in the spring. As a stop-gap solution, users were provided a simpler, yet functional, plain text editor. Once the patching was complete, MITRE re-enabled the rich text editor and sent a notification to Repository users after receiving AHRQ approval on the notification text.

During the summer, MITRE started implementing changes to the Repository to allow for easier upgrading and maintenance. Efforts included reducing the number of third-party software dependencies and capturing metrics of site performance. Please see the Repository Performance Document²⁹ for further details. These efforts have laid the groundwork for continued efforts in Year 3 of the project to further simplify site maintenance and improve Repository robustness.

Task 7: Prototype Authoring Tool and Related APIs

In the first year of the CDS Connect project, MITRE was tasked with building a prototype CDS Authoring Tool. The CDS Authoring Tool is intended to allow people unfamiliar with CQL to develop structured, well-formatted CQL artifacts with a friendly user interface and to

²⁶ <https://www.drupal.org/sa-core-2018-003>

²⁷ <https://www.drupal.org/sa-core-2018-004>

²⁸ <https://www.drupal.org/sa-contrib-2018-021>

²⁹ CMS Alliance to Modernize Healthcare, "AHRQ CDS Connect Repository Performance Document," The MITRE Corporation, Bedford, 2018.

facilitate sharing of consistently developed, standards-based CDS for reuse across organizations. At the end of the first year, the CDS Authoring Tool was alpha proof-of-concept software. While it supported the necessary features for the first year, it was completely open access (no user accounts), had inconsistent style with the CDS Connect Repository, and was not yet released to the public. In addition, it only supported a limited set of data elements coming mainly from the domain of cholesterol management. While it proved the concept of user-friendly CDS authoring, it was not yet useful to the general CDS community. In Year 2 of the project, the CDS Authoring Tool team worked to resolve these limitations.

Early in Year 2, MITRE focused on implementing infrastructure and capabilities needed to support a public release of the CDS Authoring Tool. To allow for consistent and reproducible release builds, MITRE updated the Authoring Tool to support building Docker³⁰ images for the backend API and frontend UI servers. Along with this, MITRE worked with AHRQ to configure Continuous Integration and Deployment jobs that automate development builds and deployments, as well as support transitioning deployments from development to staging to production environments. In addition, MITRE and AHRQ created a process for provisioning user accounts using a LDAP server. MITRE then implemented support for authenticating users in the CDS Authoring Tool, providing a mechanism for users to access and edit their own artifacts without seeing any other users' artifacts. MITRE also integrated the CQL-to-Expression Logical Model (ELM) conversion service to allow users to download both the CQL and ELM representations of authored artifacts in one zip file.

To provide an improved user experience, MITRE updated the styles of the CDS Authoring Tool to match the CDS Connect Repository, including the adoption of the CDS Connect headers and footers. MITRE also created a comprehensive user guide, improved support for a wider variety of browsers, and applied other minor UI enhancements and bug fixes. In early November 2017, MITRE officially released the CDS Authoring Tool and created a link to it from the CDS Connect Repository (Figure 9).

³⁰ <https://www.docker.com/>

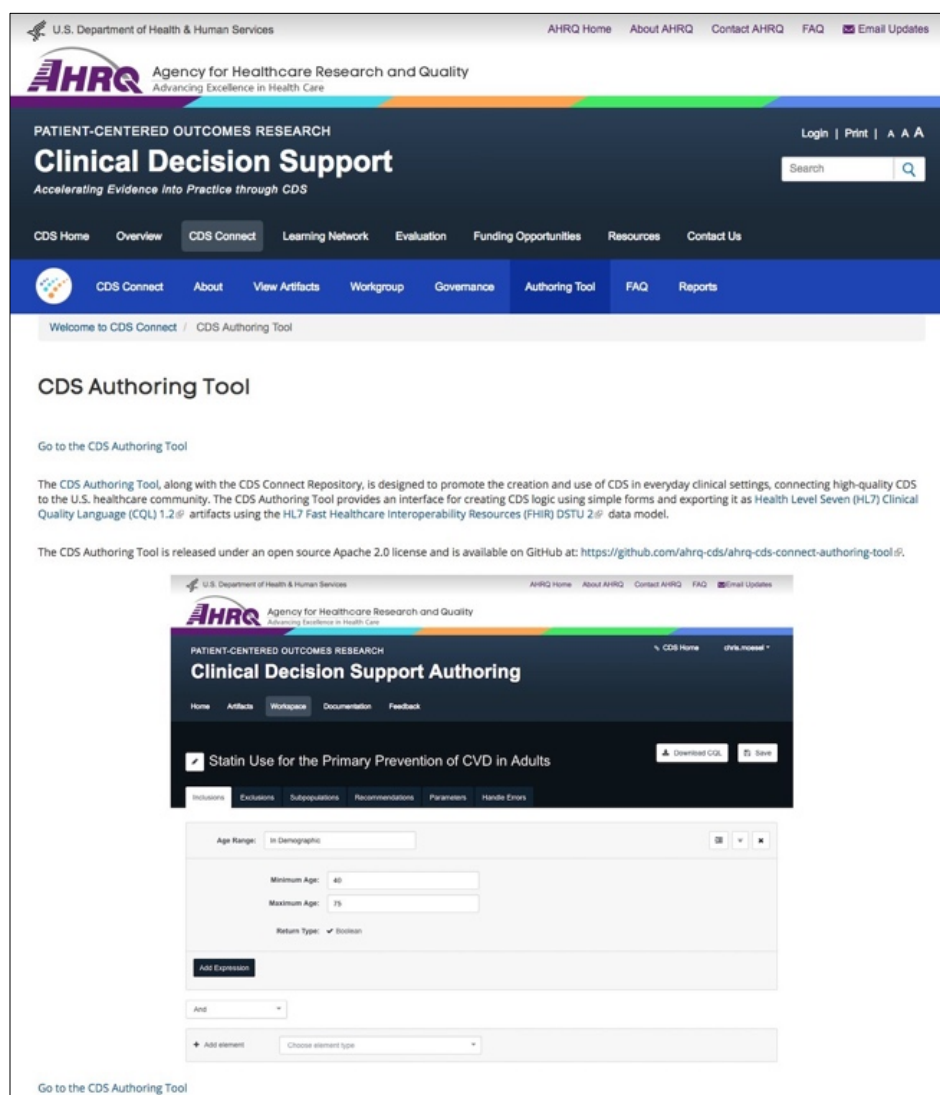
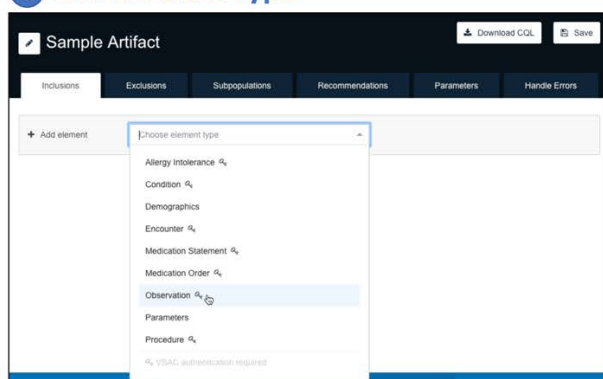


Figure 9. CDS Connect Repository Link to the CDS Authoring Tool

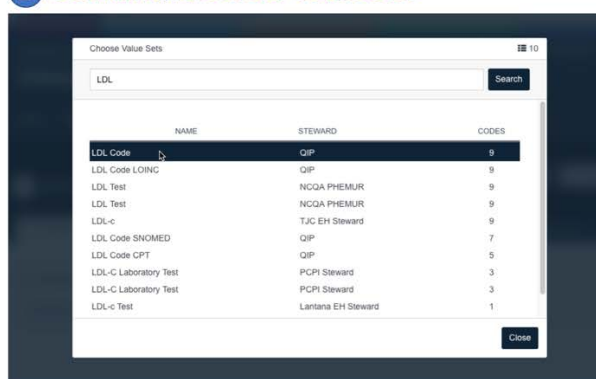
In early January 2018, MITRE delivered the beta version of the CDS Authoring Tool containing the changes described above as well as other infrastructure and user interface improvements. The beta release, however, was still restricted to elements relevant to the cholesterol management domain.

To support authoring CDS artifacts across a wide variety of clinical domains, the CDS Authoring Tool team integrated the NLM VSAC for the selection and validation of value sets and clinical codes (Figure 10). With this new capability, authors choose a basic element type and associate it with one or more value sets or codes supported by the VSAC. Currently supported basic element types include Allergy Intolerance, Condition, Encounter, Medication Statement, Medication Order, Observation, and Procedure.

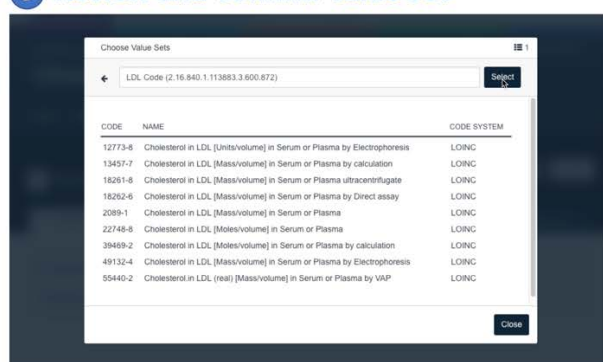
1 Choose Basic Type



2 Search and Select Value Set



3 Review and Confirm Value Set



4 Value Set Applied to Basic Type

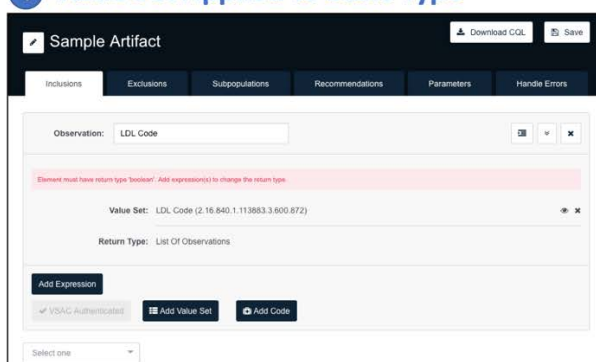


Figure 10. Sequence for Creating Element Using VSAC Integration

The CDS Authoring Tool integrates with the VSAC via the NLM's new FHIR terminology API. As part of this feature implementation, MITRE also improved the expression selectors for the basic types, including adding a smart unit search component for expressions that require a specified unit of measure. In addition, MITRE expanded support for parameter types from one type (Boolean) to 13 types: Boolean, Code, Concept, Integer, DateTime, Decimal, Quantity, String, Time, Interval<Integer>, Interval<DateTime>, Interval<Decimal>, Interval<Quantity>. Last, MITRE added user-friendly notifications and error messages informing the user when data types must be further refined or when logical constructs failed validation.

In May 2018, MITRE delivered these enhancements as the production release of the CDS Authoring Tool. The production release represented a significant improvement over the beta release, most notably opening authored CDS logic to a much wider set of clinical domains.

After the production release, MITRE began work on "expression phrases," a new feature to provide authors with a simpler summary of the data elements they have created (Figure 11). These phrases summarize data elements and their applied expressions in simple sentences. In


a future version of the CDS Authoring Tool, these expression phrases will be used to provide compact views of inclusion and exclusion criteria.

The screenshot displays the CDS Authoring Tool interface. At the top, the 'Observation' field contains the text 'LDL-c >= 130 mg/dL'. To the right of this field are three icons: a list icon, a dropdown arrow, and a close 'X' icon. Below the observation field, a text box contains the natural language expression: 'There exists a **most recent** **verified** observation with a code from **LDL-c** whose value is **greater than or equal to 130 mg/dL** .'. Below this, the 'Value Set' is listed as 'LDL-c (2.16.840.1.113883.3.117.1.7.1.215)' with an eye icon and a close 'X' icon. The 'Expressions' section lists 'Verified', 'Most Recent', and 'Quantity Value'. Below these, a row of input fields shows the comparison '>=', a unit dropdown 'x', the value '130', a 'maxOp' dropdown, the label 'maxValue', the unit 'mg/dL', and a search icon, with a close 'X' icon on the far right. The 'Return Type' is set to 'Boolean' with a checkmark icon. At the bottom, there are three buttons: 'Add Expression', 'Add Value Set' (with a list icon), and 'Add Code' (with a code icon). A status bar at the very bottom shows 'VSAC Authenticated' with a checkmark icon.

Figure 11. Expression Phrases in Complex Data Elements

At the end of Y2, MITRE also introduced an initial version of CDS testing capability. This new capability allows users to upload synthetic patient data in FHIR DSTU2 format and execute authored CDS against them (Figure 12). Using this capability, authors can verify that the logic they have created works as intended throughout the authoring process (Figure 13). The initial version supports testing against one patient at a time, but future versions may support testing against entire populations of patients.

Home
Artifacts
Workspace
Testing
Documentation
Feedback



Drop a valid JSON FHIR DSTU2 bundle containing a patient here, or click to browse.

Execute CQL for a patient below.



NAME	GENDER	BIRTH DATE	LAST UPDATED	VSAC Authenticated
Albertina684 Homenick806	female	1995-06-22	10 days ago	 Execute CQL Delete
Alfredo17 Cabán897	male	1992-09-30	10 days ago	 Execute CQL Delete

Figure 12. CDS Testing Screen Supporting Patient Upload and CQL Execution

CQL Execution Results

Patient: Albertina684 Homenick806
Artifact: Statin Use for the Primary Prevention of CVD in Adults

MeetsInclusionCriteria	✓
MeetsExclusionCriteria	✗
Recommendation	Start low to moderate intensity lipid lowering therapy based on outcome of shared decision making between patient and provider.
Rationale	The USPSTF found adequate evidence that use of low- to moderate-dose statins reduces the probability of CVD events (MI or ischemic stroke) and mortality by at least a moderate amount in adults aged 40 to 75 years who have 1 or more CVD risk factors (dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year CVD event risk of 10% or greater.
Errors	No Value

Figure 13. Example CDS Testing Results for a Synthetic Patient Matching the Inclusion Criteria

Feedback regarding the CDS Authoring Tool has been positive, and demonstrations have attracted attention at conferences such as HIMSS and AMIA. When CDS Authoring Tool topics are brought to the CDS Connect Work Group, they always generate discussion among participants. In Y2, the first year that the CDS Authoring Tool was available to the public, 89

people signed up for Authoring Tool accounts. It is unclear how many users have leveraged the CDS Authoring Tool to create production artifacts, but recent enhancements, as well as several related AHRQ CDS initiatives, are expected to encourage more use of the Authoring Tool in the coming year.

In Year 3, MITRE plans to introduce a capability to author standalone elements that can be referenced multiple times in the same artifact and/or used outside the context of inclusion and exclusion criteria. This capability was nearly complete at the end of Y2 but had not yet been released. In addition to this, MITRE plans to further enhance the synthetic testing capability and to provide additional features supporting more flexibility in authoring CDS logic outside the constructs currently supported.

7.1 Open Source Status

From the start of development in the first year of the project, MITRE and AHRQ have been planning to release the CDS Authoring Tool as open source for many reasons, including:

- Open source code allows the community to modify and enhance the CDS Authoring Tool and optionally contribute these changes back to the project
- Organizations that prefer to develop CDS in house can do so by downloading and installing the open source code locally
- Organizations developing CDS authoring capabilities can learn from or leverage CDS Authoring Tool code, helping to drive CQL adoption further
- Open source development offers greater transparency and establishes trust within the community
- Members of the CDS Connect Work Group and the CDS community expressed continued interest in an open source release of the CDS Authoring Tool

In March 2018, CDS Connect announced the open source release of the CDS Authoring Tool. The CDS Authoring Tool is released under the Apache 2.0³¹ license and is available on GitHub at: <https://github.com/ahrq-cds/ahrq-cds-connect-authoring-tool> (Figure 14).

³¹ <https://www.apache.org/licenses/LICENSE-2.0>

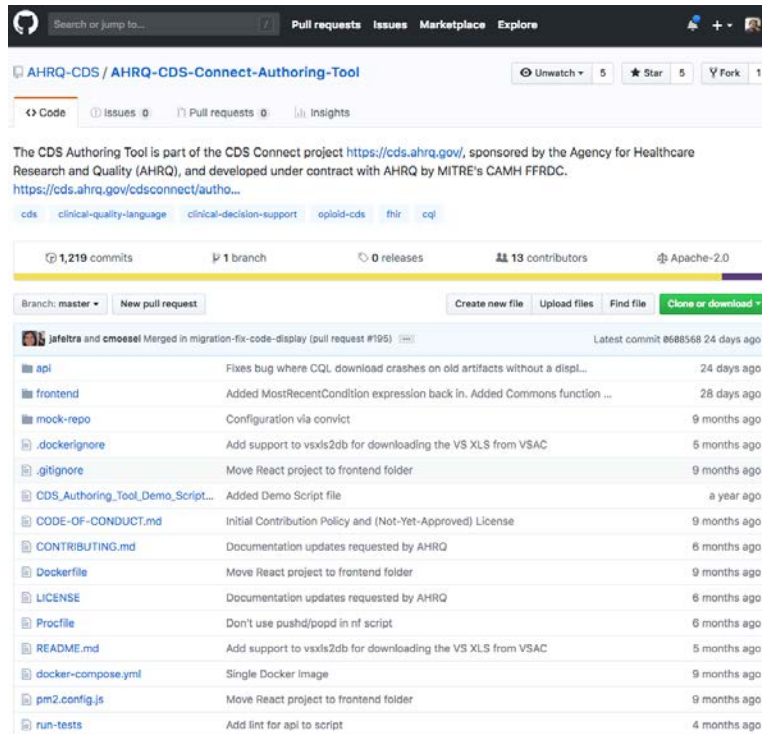


Figure 14. The CDS Authoring Tool on GitHub

Lessons Learned

Through the CDS Connect project's second year, several valuable lessons were learned that both impacted Y2 work and provided critical information with which to plan for the project's third year.

1. **Software testing:** Testing of software updates for the Repository are currently done in a mostly manual fashion. This is time consuming and prone to human errors, as was seen with the LDAP issue briefly experienced in July. Automated testing of the software should be considered as a more robust and efficient approach.
2. **CDS Authoring Tool VSAC Integration:** The initial VSAC integration in the CDS Authoring Tool used the NLM Sharing Value Sets version 2 APIs. These APIs did not support searching value sets, requiring MITRE to develop a custom solution. In discussions with NLM, MITRE discovered that NLM had recently released a FHIR terminology API that met 95 percent of the Authoring Tool requirements. NLM agreed to implement the gap in requirements and when it was ready, MITRE switched from its custom search solution to the NLM FHIR terminology API. Had the Authoring Tool team engaged NLM earlier in the effort, it might have been possible to avoid the need for a custom solution.

3. **Pilot CDS integration:** Integration of the CDS at the pilot site required engineering effort from the piloting organization and the CDS Connect project team. The CDS Connect team did not have direct access to testing or production pilot systems, making debugging and performance testing very difficult. In future pilot efforts, access to testing environments (even if supervised) can likely make integration more efficient.
4. **Pilot FHIR support:** While the piloting organization's EHR provided a FHIR API, many of the concepts needed by the CDS were not exposed through the FHIR API. This was especially true of pain assessments, which were captured as structured data but were not available in the FHIR API. This required custom development by the piloting organization. In future pilot efforts, these limitations should be considered.
5. **Stakeholder engagement:** Engagement with the CDS community is vital to ensure that the systems developed by the project team align with the community's needs. Engagement via outreach, collaboration, partnerships, discussions, and presentations also serves to spur contributions to the Repository and use of the Authoring Tool, increasing the likelihood of sustained use of the systems.
6. **Environmental scan:** An environmental scan at the outset of research on the identified clinical domain, relevant evidence-based sources, previously implemented CDS interventions and lessons learned, and identified challenges and constraints leads to valid, implementable, reliable CDS expressions.
7. **Selection of CDS for development:** Providing CDS options to pilot sites (as opposed to only offering one CDS intervention), enables potential pilot partners to select an intervention that aligns with organizational goals, is most implementable in their system, might most resonate with their providers, and might be the most accurate and reliable given known data constraints. A "one size fits all," or "if you build it, they will come" approach introduces a challenge to securing pilot site agreement and the success of the piloted artifact.
8. **Engaging with terminology organizations:** When gaps in standard terminologies are identified, do not hesitate to reach out to terminology organizations. LOINC representatives were very receptive to learning of identified gaps and were eager to support external stakeholder assistance with closing the gap. Use of standardized codes is key to interoperable artifacts, and missing codes cannot be assigned if the terminology steward is unaware of the gap and/or need.
9. **Identifying value sets:** CDS and eQIM developers should strive to reuse existing value sets whenever possible, but when value sets are published outside of commonly used

databases (e.g., VSAC), they are hard to find. A more informed, purposeful search at the onset of CDS work may yield additional resources that were not initially identified.

10. **Collaboration with knowledge authors and stewards:** Having knowledge authors and stewards (e.g., a program office that oversees a clinical practice guideline) participate in the translation of the evidence to CDS will enable informaticists and software engineers to accurately code the CDS artifact, driving the delivery of evidence-based CDS interventions.
11. **Supporting artifact contributions to the Repository:** CDS developers are the best positioned to contribute artifacts, but if the development project has ended, they often do not have the time or bandwidth to manually enter metadata responses and add attachments. Having volunteers or others draft the metadata to facilitate the upload is not a sustainable process. Continued enhancements to the Repository API to support automated upload of artifacts is vital to accelerating contributions.
12. **The value of Work Group feedback:** The varied, real-world experience and insight provides major value to project efforts. Ensuring that systems and resources produced by CDS Connect are informed by stakeholder feedback amplifies the usefulness and longevity of the systems.
13. **Intellectual property constraints:** IP restrictions are present on many of the evidence-based research, clinical practice guidelines, and clinical tools available to the public. Efforts to engage with IP holders and gain formal approval to express components of their work as CDS take a considerable amount of time, jeopardizing the project timeline and therefore the ability to use IP restricted content.

Recommendations

The CDS Connect team recommends the following activities for the third year of the project:

1. **Automate Repository testing:** While the issues identified in this and other reports are quite minor, automated testing should be added to the Repository to reduce the likelihood of software issues on the production version of the Repository.
2. **Enhance the Repository APIs:** This will facilitate adding more artifacts to the Repository.
3. **Support other versions of FHIR in the CDS Authoring Tool:** While FHIR DSTU2 currently enjoys the most industry adoption, FHIR Standard for Trial Use 3 (STU3) and the upcoming Release 4 (R4) may begin to gain more support. The CDS

Authoring Tool should consider supporting the export of artifacts in these updated formats.

4. **Support additional terminology servers in the Authoring Tool:** While the VSAC offers many value sets, some organizations prefer to use other terminology servers. The CDS Authoring Tool should consider supporting value set searching and retrieval using other terminology servers.
5. **Support importing external CDS in the CDS Authoring Tool:** The CDS Authoring Tool cannot generate every possible form of CQL logic, so it should allow the import of CQL libraries to support logical constructs not possible through the Authoring Tool UI.
6. **Continue to allow pilot sites to select and shape the CDS:** This enhances the “win” for the pilot organization to partner in the effort and improves the value and effectiveness of the implemented CDS.
7. **Collaborate with other government entities developing CDS:** There are significant opportunities to leverage knowledge, resources, and tools across many Government projects. Maintaining regular communication with these stakeholders and exploring where efforts can be harmonized and accelerated will enable greater impact.
8. **Collaborate with related efforts:** Other groups are trying to advance the translation of knowledge into computable artifacts to be implemented in clinical systems (e.g., *Mobilizing Computable Biomedical Knowledge* and *Adapting Clinical Guidelines for the Digital Age*). Collaboration with these efforts will inform and augment overarching objectives.
9. **Continue outreach and engagement via presentations and demonstrations at conferences and webinars:** This will raise awareness of project efforts and help to identify new stakeholders and collaboration opportunities.
10. **Explore new CDS intervention types, delivery channels, and targeted end users:** Structured artifacts, open source tools, and lessons learned documented during artifact development and pilot implementation and shared via the Repository provide valuable information and resources to the CDS community. Exploring new aspects of the “5 Rights” Framework will enhance what is already available, with the caveat that technical resources, capabilities, and infrastructure, along with the level of effort to integrate the CDS must be feasible for potential pilots.